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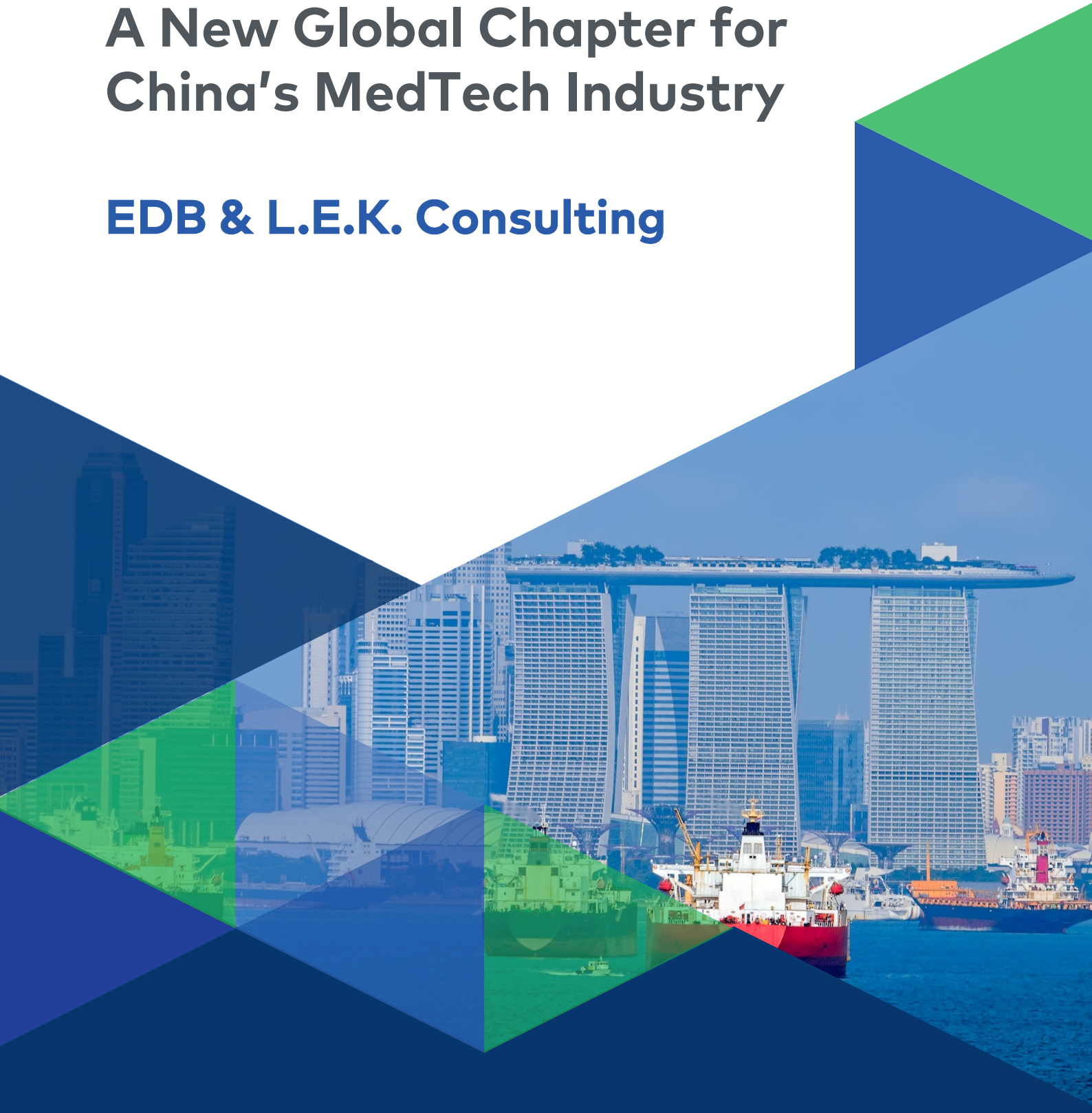
Rising Tide in Southeast Asia: A New Global Chapter for China's MedTech Industry

EDB & L.E.K. Consulting



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Executive summary

Against the backdrop of volume-based procurement becoming the norm, deeper payment reform and intensifying industry competition, China's medtech sector is at a critical inflection point from domestic circulation to globalization. Margin pressure and structural competition in the domestic market are accelerating companies' international expansion. At the same time, policy support for innovation and overseas growth, together with the demonstration effect of innovative biopharma going global, is opening up new avenues of growth for medtech companies abroad.

Southeast Asia has emerged as a preferred destination for Chinese medtech companies expanding overseas, supported by geographic proximity, favorable demographics, rapidly growing healthcare demand and a relatively friendly market access environment. Within the region, Singapore is increasingly becoming a strategic beachhead for companies seeking to deepen their Southeast Asia presence, underpinned by its well-developed industrial base, efficient institutions, mature ecosystem and distinctive geographic position. First, Singapore has built a complete industry ecosystem spanning manufacturing, innovation, R&D and talent supply. Second, its efficient regulatory system and flexible international recognition can significantly improve regional registration and market access efficiency. Third, its mature industry-academia-research-clinical innovation ecosystem provides strong support for technology collaboration and commercialization. Fourth, as a two-way gateway linking Southeast Asia, the broader Asia-Pacific and global markets, Singapore plays a critical role as both a regional hub and an accelerator in supporting the global expansion of Chinese medtech companies.

1. China medtech: Going global at the right time

Alongside the continued expansion of volume-based procurement and accelerated implementation of payment reform, China's medtech industry is undergoing a deep transition from rapid growth to high-quality development. As the regulatory system continues to improve and market mechanisms become more mature, the domestic competitive landscape has shifted from incremental expansion to competition within existing demand, with intensifying pressure from product homogeneity. Policy and market forces are jointly reshaping the industry ecosystem. On the one hand, government support for technological innovation and international expansion, reinforced by the demonstration effect of innovative biopharma going global, is creating external pull and new growth opportunities for medtech companies. On the other hand, institutional changes such as volume-based procurement and payment reform are pushing the industry into a normalized cost-containment phase, creating internal pressure for companies to transform and upgrade.

Under the combined effect of these pull and push factors, China's medtech industry is approaching a critical inflection point from domestic circulation to globalization. Going global is no longer optional but a strategic imperative for companies seeking sustainable growth.

Pull factor 1: The Chinese government is using technological innovation as a strategic driver to encourage companies to expand globally

With technological innovation as a core growth engine, the Chinese government has continued to introduce policies and incentives to encourage medtech companies to expand overseas and build end-to-end global capabilities across R&D, manufacturing, registration and commercialization. Supported by a more complete policy framework and innovation ecosystem, Chinese companies can not only strengthen technological capabilities and international competitiveness in overseas markets but also accelerate the global adoption of high-end medical devices and digital health solutions, thereby securing a more important position in the global medtech industry.

Pull factor 2: Southeast Asia's medtech market is growing rapidly, prompting faster expansion by Chinese companies

Global medtech markets offer significant headroom, with Southeast Asia standing out as a particularly attractive growth market and opening a window for Chinese companies to accelerate expansion in the region. Driven by favorable demographics, healthcare service upgrades and supportive regional policies, demand for high-quality medical devices is rising rapidly across Southeast Asia. At the same time, improving healthcare infrastructure and

accelerating digital transformation are creating additional opportunities for market entry and expansion. Against this backdrop, Chinese medtech companies are stepping up their Southeast Asia presence through a range of strategies, including localized manufacturing, distributor network build-out, partner expansion and M&A, in order to capture growth opportunities and strengthen global competitiveness.

Pull factor 3: Chinese medtech is moving up the innovation curve, with customer demand and market recognition rising in parallel

Chinese medtech is evolving from "the world's factory" into a source of global innovation, with customer demand and market recognition continuing to improve. As R&D capabilities strengthen and more high-end medical devices and digital health products emerge, Chinese companies are becoming more internationally competitive in terms of quality, performance and service, earning broader recognition in overseas markets. At the same time, rising demand for innovative products across the global healthcare market is creating opportunities for Chinese companies to expand into higher-value segments. In this context, Chinese medtech companies are actively building global footprints across R&D, manufacturing, registration and commercialization through in-house innovation, collaborative development and localized operations, enabling a strategic transition from manufacturing to innovation.

Push factor 1: Cost-control pressures driven by healthcare policy reform

As policies such as volume-based procurement and payment reform continue to advance, Chinese medtech companies are facing mounting cost-control pressure. On the one hand, volume-based procurement has driven product prices down rapidly, compressing profit pools. On the other hand, changes in reimbursement standards, together with tighter cost constraints at the hospital level, are placing increasing limits on investment in channels, manufacturing and commercial promotion. Under this dual pressure, companies must improve manufacturing efficiency, optimize supply chain structures and accelerate technological innovation in order to build more refined cost management and more resilient operating models.

Push factor 2: Severe supply-side homogeneity and increasingly visible structural challenges

China's medtech industry includes a large number of companies and a broad industrial base but overall remains concentrated in low-to-mid-end products, with clear gaps in core technologies and high-end supply. As supply-side structural reform continues to advance, homogenous competition is further compressing profit pools, making it increasingly urgent for companies to identify new growth engines.

1.1. Pull factors: Policy support and international market opportunities

1.1.1. Pull factor 1: The Chinese government is using technological innovation as a strategic driver to encourage companies to expand globally

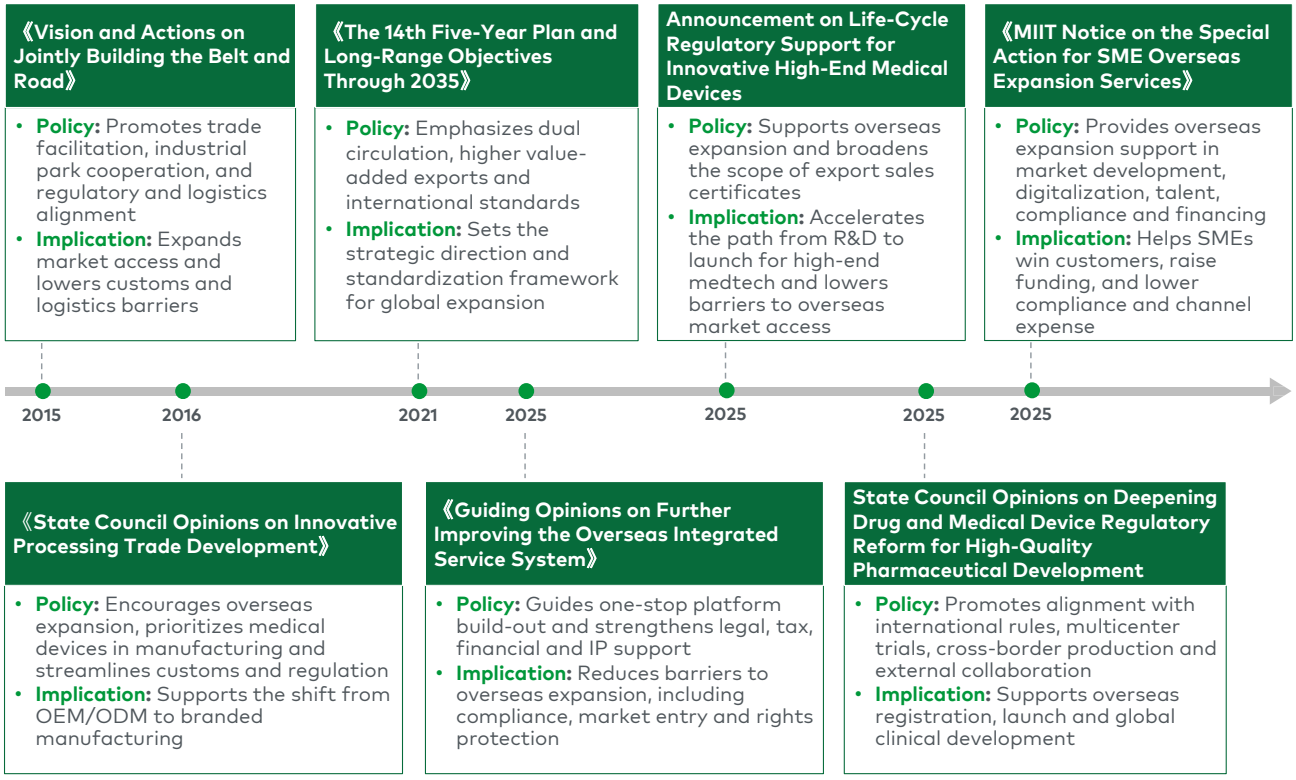
National policy continues to encourage companies to expand overseas and build international businesses, providing strong support for the global expansion of innovative medical devices. Since the launch of the Belt and Road Initiative in 2015, China has positioned international industrial cooperation and the global expansion of high-end manufacturing as key strategic priorities, encouraging technology-advantaged sectors such as medtech to accelerate the growth of their global footprint. Since then, relevant authorities have introduced a series of policies providing systematic support for international expansion across funding, trade, certification and intellectual property protection.

During the 14th Five-Year Plan period, policy direction has become more focused on innovation-driven growth and systematized globalization. China has called for the development of world-class advanced manufacturing clusters and has built a multil ayered coordination mechanism across trade, technology and industrial policy to accelerate the internationalization of innovative products and high-end equipment. In 2025, the General Office of the Ministry of Industry and Information Technology issued the Notice on Launching a Special Action for Supporting Small and Medium-Sized Enterprises (SMEs) in Going Global, calling for improvements to the overseas expansion service system, the development of international cooperation platforms and stronger guidance on overseas market access and compliance, thereby providing SMEs with full-cycle, end-to-end support for global expansion.

At the policy system level, China has established a relatively complete support chain for overseas expansion spanning R&D, registration and trade. Strategies such as technology innovation initiatives and key R&D programs for high-end medical equipment are helping companies build core technologies and strengthen product competitiveness. At the same time, China is streamlining medical device export registration and overseas certification processes while encouraging companies to participate in the development of international standards to improve global recognition. Policy support also extends to finance, taxation and trade infrastructure, including export tax rebates, overseas warehouse deployment and cross-border eco mmerce platform development, providing institutional support to reduce the cost of going global and expand international market access.

Overall, from 2015 to 2025, China's internationalization strategy for the medtech sector has evolved from encouraging companies to go global to providing systematized support for global expansion. This shift not only reflects the deepening of China's broader opening-up agenda but also provides a strong policy foundation and greater confidence for innovative medtech companies pursuing global growth.

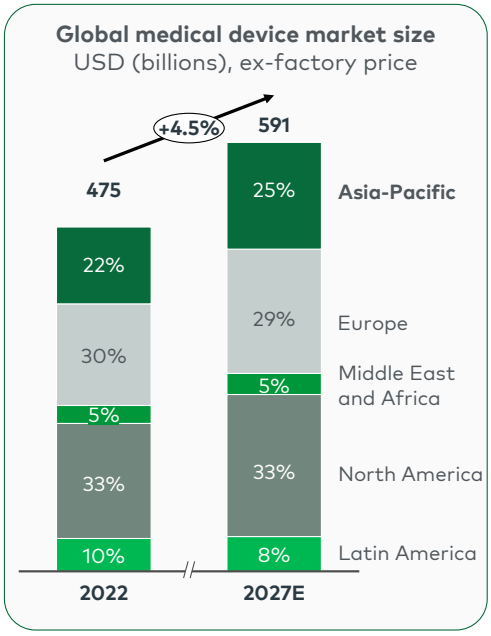
Chinese government policies supporting innovative medtech going global

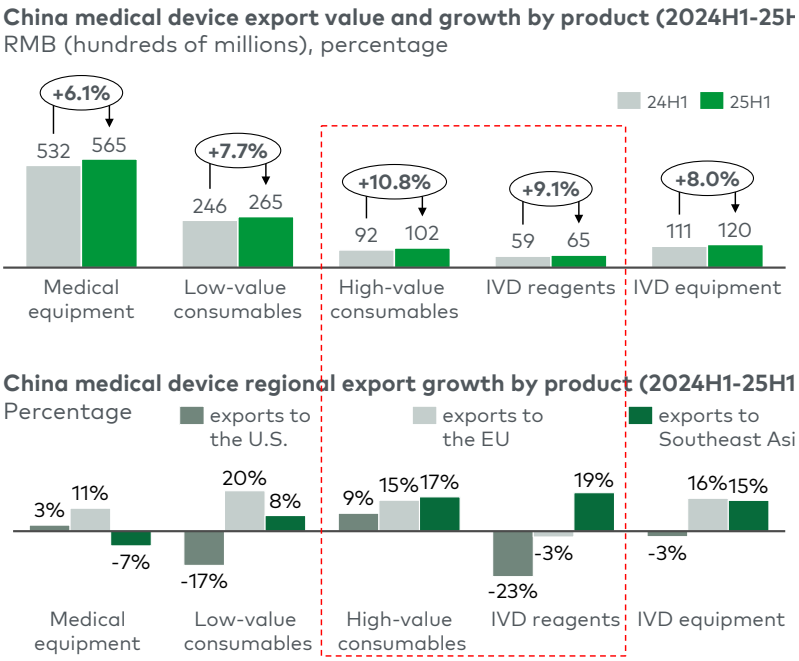


Note: MIIT=Ministry of Industry and Information Technology; SMEs=small and medium-sized enterprises; IP=intellectual property; OEM=original equipment manufacturer; ODM=original design manufacturer
Source: Public information; L.E.K. analysis

1.1.2. Pull factor 2: Southeast Asia's medtech market is growing rapidly, prompting faster expansion by Chinese companies

The Chinese government is using technological innovation as a strategic driver to encourage companies to expand globally. Through a series of policies and support measures — including incentives for R&D investment, intellectual property protection, greater ease in international registration and standards alignment, and guidance on exports and overseas investment — Chinese companies have gained institutional support for global expansion. These measures not only help strengthen innovation capabilities but also accelerate the internationalization of higher-barrier products such as high-value consumables and in vitro diagnostic (IVD) reagents, enabling Chinese medtech companies to enhance competitiveness in global markets while achieving parallel gains in innovation and scale.

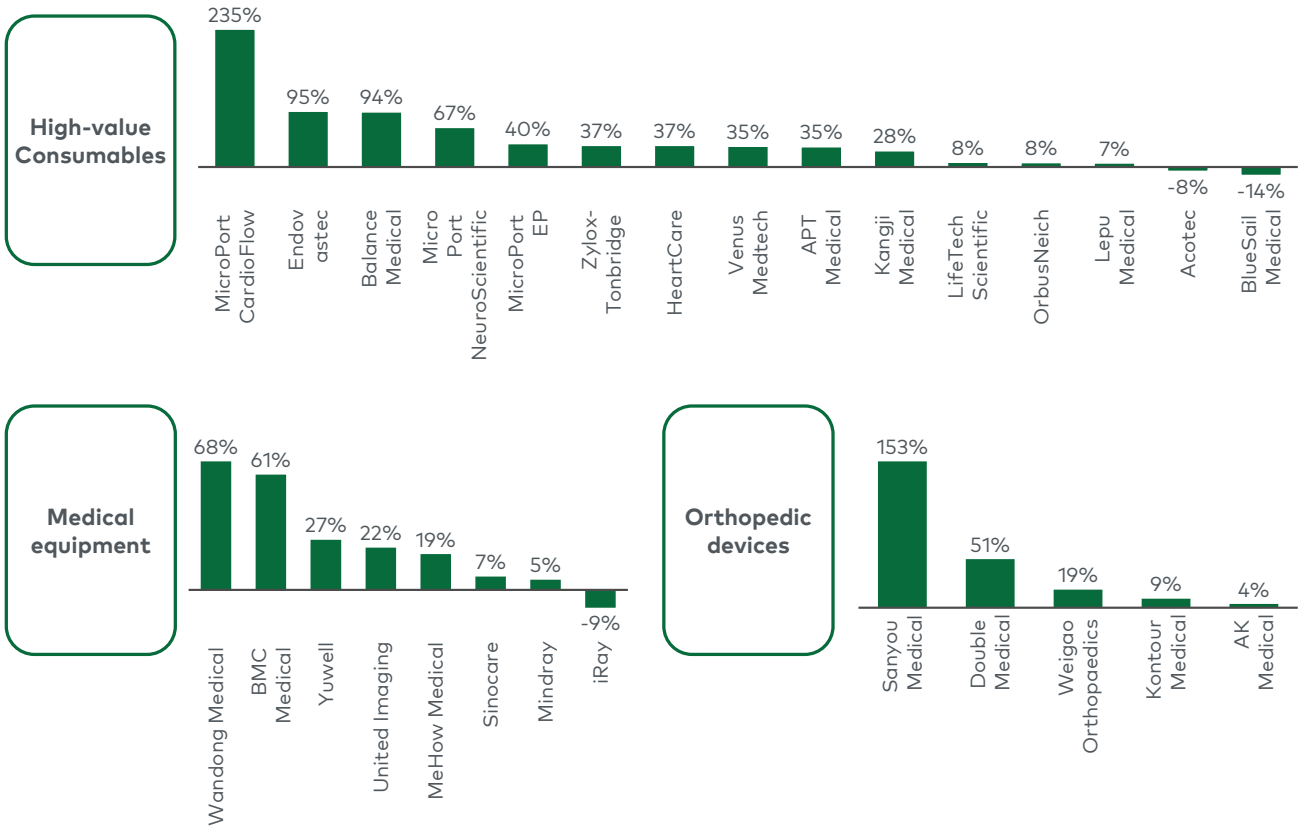




Note: IVD=in vitro diagnostic
Source: General Administration of Customs of China; China Federation of Logistics & Purchasing Medical Device Supply Chain Branch; IQVIA database; L.E.K. analysis

Leading Chinese medtech companies are delivering rapid growth in overseas revenue, underscoring strong international expansion momentum. Based on 2024-2025 data, core categories such as high-value consumables, medical devices and orthopedic devices have posted notably strong year-over-year overseas revenue growth among China's leading players. In particular, exports of high-value consumables and IVD reagents to Southeast Asia have accelerated significantly, highlighting these companies' growing ability to expand internationally in high-barrier, high-value product segments. This trend suggests that as companies accelerate overseas expansion and global market build-out, leading players are gaining an early advantage in key categories, sustaining strong overall overseas revenue growth and laying the groundwork for further expansion across Southeast Asia and other international markets.

YoY growth in overseas revenue of leading Chinese medtech companies (2024H1-25H1)
Percentage



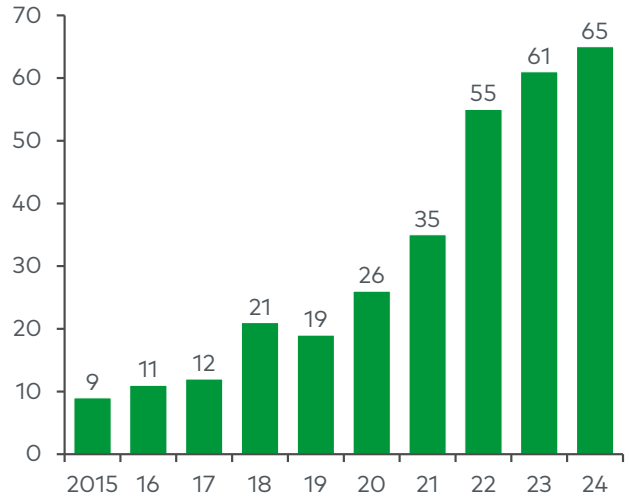
Note: YoY=year over year
Source: Company annual reports; Wind; L.E.K. analysis

1.1.3. Pull factor 3: Chinese medtech is moving up the innovation curve, with customer demand and market recognition rising in parallel

Driven by sustained R&D investment, Chinese medtech companies are accelerating their transition from global manufacturers to innovation leaders, with approvals of breakthrough medical devices rising significantly. Over the past decade, the number of innovative medical devices approved in China has shown a steady and resilient upward trend, reflecting continued deepening of corporate R&D activity and faster translation of innovation into approved products. This shift is not the result of short-term policy stimulus, but rather the outcome of a sustained increase in R&D intensity among leading companies over time. A growing number of companies are treating R&D as a core capability, with R&D spending as a share of revenue remaining at relatively high levels and providing strong support for the continued launch of innovative devices.

As innovation continues to scale domestically, the technological capabilities of Chinese medtech companies are also beginning to gain recognition in high-standard international markets. Multiple companies have received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for innovative products. Designed to accelerate the review of products with meaningful clinical value, this pathway signals that original Chinese technologies are increasingly entering the global innovative medtech landscape and are now in a phase of rapid expansion.

Number of innovative medical devices approved in China* (2015-24)
Cases



Sustained R&D is accelerating medtech innovation and breakthrough approvals in China

Domestic innovation gaining traction

- Driven by sustained R&D, Chinese medtech companies are shifting from global manufacturers to innovation leaders. Rising domestic approvals of innovative devices validate improving R&D capabilities.

International recognition and breakthroughs

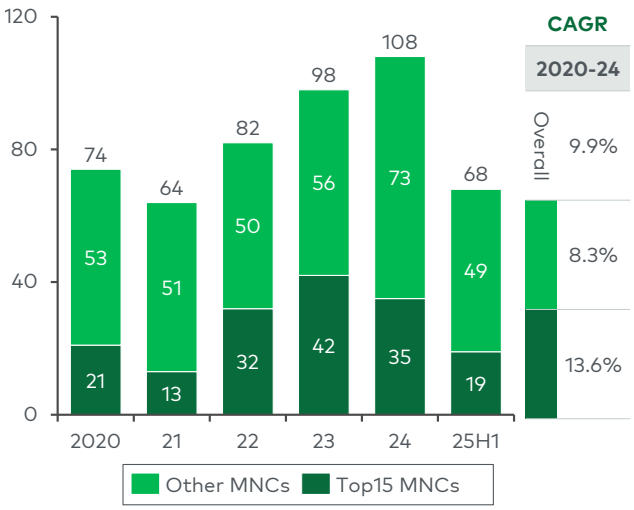
- Products from multiple Chinese companies, including Pulnovo Medical, Burning Rock and Sinomed, have received FDA Breakthrough Device designation. This indicates growing international recognition of Chinese medtech innovation and a rapid development phase.

*Innovative medical devices are devices recognized by the NMPA as demonstrating significant technological innovation and clinical value
Note: NMPA=National Medical Products Administration; FDA=U.S. Food and Drug Administration
Source: National Medical Products Administration; U.S. Food and Drug Administration; company annual reports; Frost & Sullivan report; L.E.K. analysis

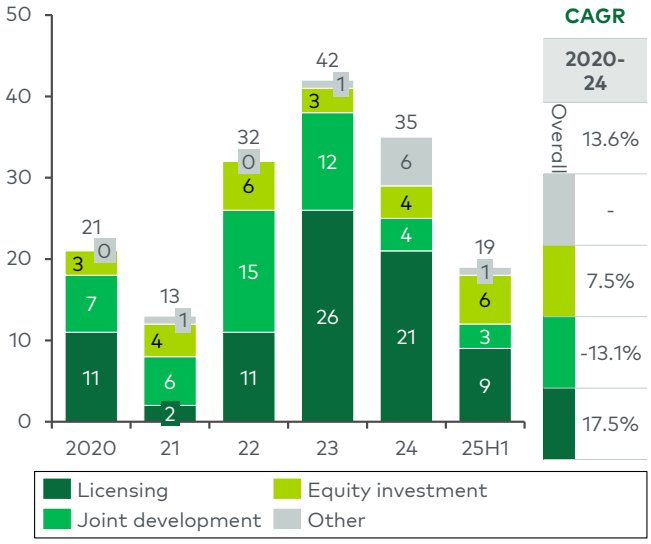
The sharp increase in out-licensing and business development deals for Chinese innovative drugs has reduced uncertainty and lowered negotiation barriers, providing a clear precedent and greater confidence for medtech companies pursuing global expansion. Backed by original technologies and differentiated clinical value, Chinese innovative biopharma companies are accelerating licensing partnerships globally, with deal structures spanning single-asset licensing, co-development and platform collaborations, while both deal size and strategic importance continue to rise. This trend highlights the growing international recognition of Chinese innovation and provides a relevant path for medtech companies going global: By strengthening technological innovation, international partnerships and brand building, companies can accelerate global expansion while drawing on innovative biopharma's experience in registration, compliance and market access to reduce execution risk and enhance international competitiveness.

Overall, the internationalization wave of innovative biopharma in recent years has not only validated the global innovation potential of China's healthcare industry but also provided strategic reference points and confidence for medtech companies expanding overseas, marking a critical window in which medtech globalization is both increasingly viable and accelerating.

Number of China pharma business development deals (by buyer type) (2020-25H1)
Cases



Number of top 15 MNC* pharma company deals (by deal type) (2020-25H1)
Cases



*Top 15 MNCs with the highest deal activity in 2020-1H25
Note: MNC=multinational corporation; CAGR=compound annual growth rate
Source: Cortellis; DXY; L.E.K. analysis

1.2. Push factors: Domestic competition and the policy environment

1.2.1. Push factor 1: Cost-control challenges arising from healthcare policy reform

China's value-based procurement model for medical devices has entered a normalized phase, with coverage expected to exceed 50% by the end of 2026 and drive significant price reductions; cuts in national centralized procurement typically exceed 50% and can reach as high as 90%.

VBP has become normalized and institutionalized

- The 2021 guideline formalized the "national organization-alliance procurement-platform execution" model, marking **the institutionalization of medtech VBP**
- In 2024, the NHSA and NHC further clarified VBP requirements across hospital access, prioritized use, monitoring, pricing and supply
- The new rules strengthened execution and reinforced **VBP as a normalized mechanism**

VBP is expanding nationally and regionally

- Since 2020, **national VBP has expanded steadily**; by mid-2025, five rounds had covered coronary stents, orthopedics, intraocular lenses, cochlear implants and peripheral vascular stents
- In 2024, the NHSA called for stronger regional coordination, with provinces leading procurement beyond national VBP categories
- **National and provincial procurement operate complementarily**

End-to-end constraints on non-winning products

- Policies are systematically narrowing the pricing and usage room for non-winning products through preferred use of winning products, price benchmarking and listing management, payment caps, and higher online procurement rates
- Enforcement is also growing stronger through inspection audits and other regulatory measures, creating **end-to-end constraints on non-winning products**

VBP is driving sharp price cuts in medical devices

- In recent years, medical devices included in VBP have seen **average price cuts of over 50%**, with national VBP categories down ~65%-95%
- **In orthopedics, VBP coverage exceeds 90%,** making it one of the most affected segments
- In vascular intervention, coronary and peripheral vascular stents are included in national VBP; in ophthalmology, intraocular lenses are also included, **with price cuts of over 60%**

Note: VBP=value-based procurement; NHSA=National Healthcare Security Administration; NHC=National Health Commission
Source: L.E.K. analysis

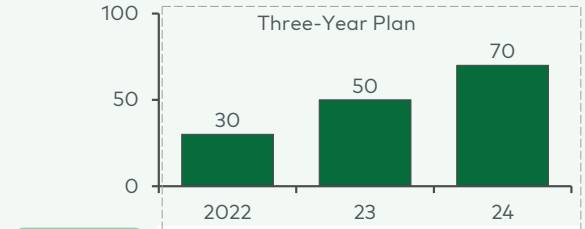
The continued deepening of payment reform is reshaping both the cost structure of healthcare providers and the logic underpinning procurement decisions. To support more refined management of medical insurance funds and more efficient allocation of healthcare resources, China first launched payment reform pilots centered on diagnosis-related groups (DRGs) and diagnosis-intervention packets (DIPs), and has gradually scaled these reforms nationwide. Below is a timeline of China's DRG/DIP payment reform, illustrating the evolution of the policy framework and the accelerating pace of reform.

China DRG/DIP payment reform timeline

Pilot launch phase (2019-2021)	Nationwide rollout phase (2022-2023)	System upgrade phase (2024-2025)
• The NHSA designated **30+ pilot cities** for the formal launch of DRG reform. During this phase, China established the grouping system, cost benchmarks and data standards, and released CHS-DRG Grouping Scheme (Version 1.0), setting **a unified national grouping framework.**	• The Three-Year Action Plan for DRG/DIP Payment Reform (2022-2024) was released, aiming to implement DRG/DIP-based payment reform **across all regions nationwide within three years. By this stage, 90%+ of pooling areas had launched DRG/DIP**, marking a shift from pilot testing to broad-based implementation.	• The NHSA released the **DRG/DIP 2.0 framework**. Since 2025, a unified national grouping standard has applied, with 409 DRG core groups and a DIP library of 9,520 disease categories. Localities are accelerating the shift to 2.0 and refining local grouping libraries.

《Three-Year Action Plan for DRG/DIP Payment Reform》
Released by the NHSA in November 2021

Medical Insurance Funds Paid Under DRG/DIP (2022-24)
Coverage of Medical Insurance Funds (Percentage)

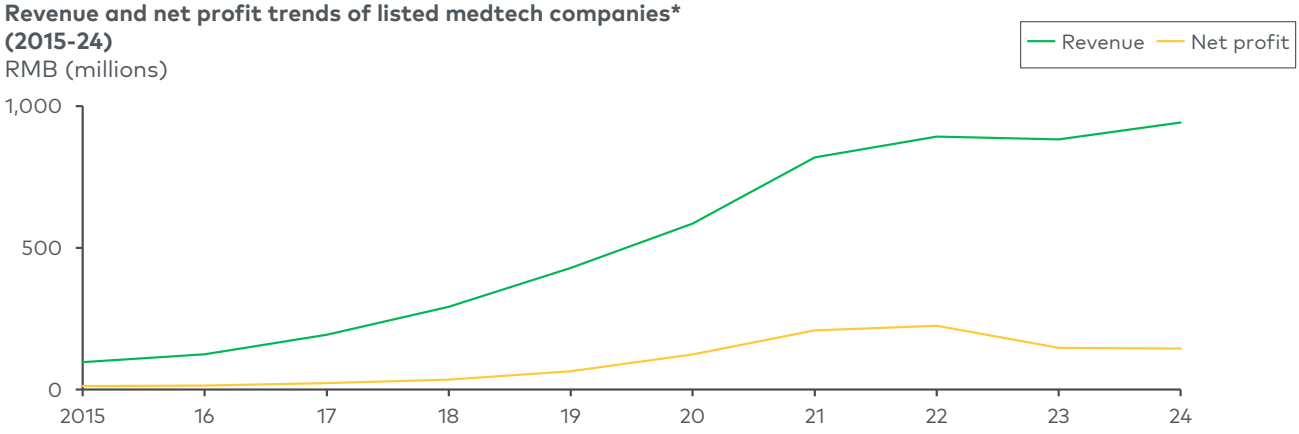


	2022	23	24
City coverage	40%	70%	100%
Institution coverage	40%	70%	100%
Disease coverage	70%	80%	90%

Note: CHS=China Healthcare Security; DRG=diagnosis-related group; DIP=diagnosis-intervention packet; NHSA=National Healthcare Security Administration
Source: State Council; NHSA; L.E.K. analysis

Volume-based procurement and hospital-side cost control together form a dual cost-containment framework for healthcare spending, with far-reaching implications for the medtech industry's profit model. Volume-based procurement is designed to reduce prices through scaled centralized purchasing, driving product prices down rapidly toward cost levels. Hospital-side cost control, by contrast, links hospital revenue more closely to reimbursement mechanisms through payment reform, making hospitals more focused on cost-effectiveness and utilization efficiency in device purchasing. This continuous cost-control pressure, extending from upstream procurement to downstream payment, has significantly compressed medtech companies' pricing power, channel margins and capacity for innovation investment, resulting in a structural decline in profitability. Companies that fail to create value through technological innovation or international expansion risk being marginalized in the next wave of industry reshuffling.

Revenue and net profit trends of listed medtech companies* (2015-24)
RMB (millions)



Revenue YoY	29%	55%	51%	47%	36%	40%	9%	⬇ -1%
Net profit YoY	17%	60%	54%	84%	92%	69%	8%	⬇ -35%

Post-VBP price cuts and cost-containment policies affecting innovative products are **squeezing corporate profit margins**

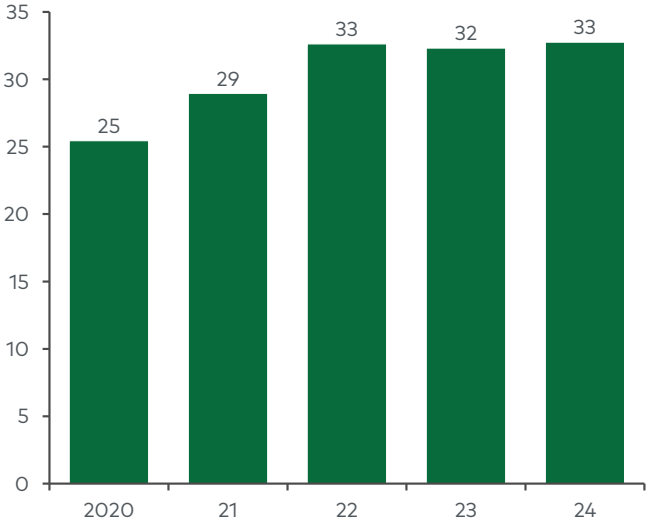
*Based on medtech sector data under the Shenwan Level 2 industry classification
Note: VBP=value-based procurement; YoY=year over year, RMB=Chinese Yuan
Source: AlphaEngine; L.E.K. analysis

1.2.2. Push factor 2: The supply base is large, but low-end products still dominate, intensifying homogenous competition

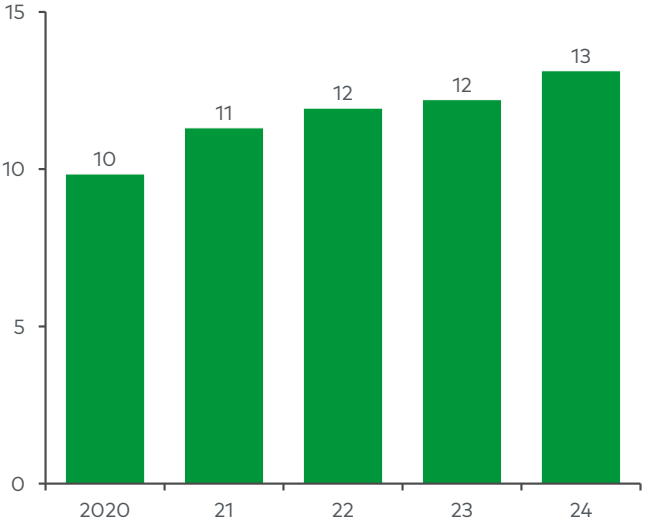
The supply side is characterized by a large number of companies and substantial product volume, yet low-end supply continues to dominate, pointing to intense homogenous competition. Supported by continued policy tailwinds and sustained demand growth, the supply base of China's medtech industry has continued to expand, with both the number of market participants and the volume of product supply rising in parallel. Over the past several years, the number of medical device manufacturers has grown steadily, indicating that the sector remains attractive to new entrants. At the same time, the number of approved medical devices has continued to increase, reflecting a further strengthening in overall product supply capacity.

The dual expansion in the number of companies and the scale of product supply underscores the core characteristics of China's medtech industry today: ample supply and a fragmented competitive landscape. This also provides important context for understanding the current market structure and the growing convergence in product offerings.

Number of medical device manufacturers in China (2020-24)
Thousands



Number of medical devices approved in China* (2020-24)
Thousands



*Includes initial registrations, renewals and registration changes
Note: NMPA=National Medical Products Administration
Source: NMPA; AskCI; L.E.K. analysis

2. Chinese medtech companies expanding into Southeast Asia: Typical pathways and case studies

There are several key strategic considerations for Chinese medtech companies going global — from market selection to winning locally. In this process, companies need to systematically assess target market potential, product and capability fit, and localization and competitive strategy to ensure successful overseas expansion and sustainable growth.

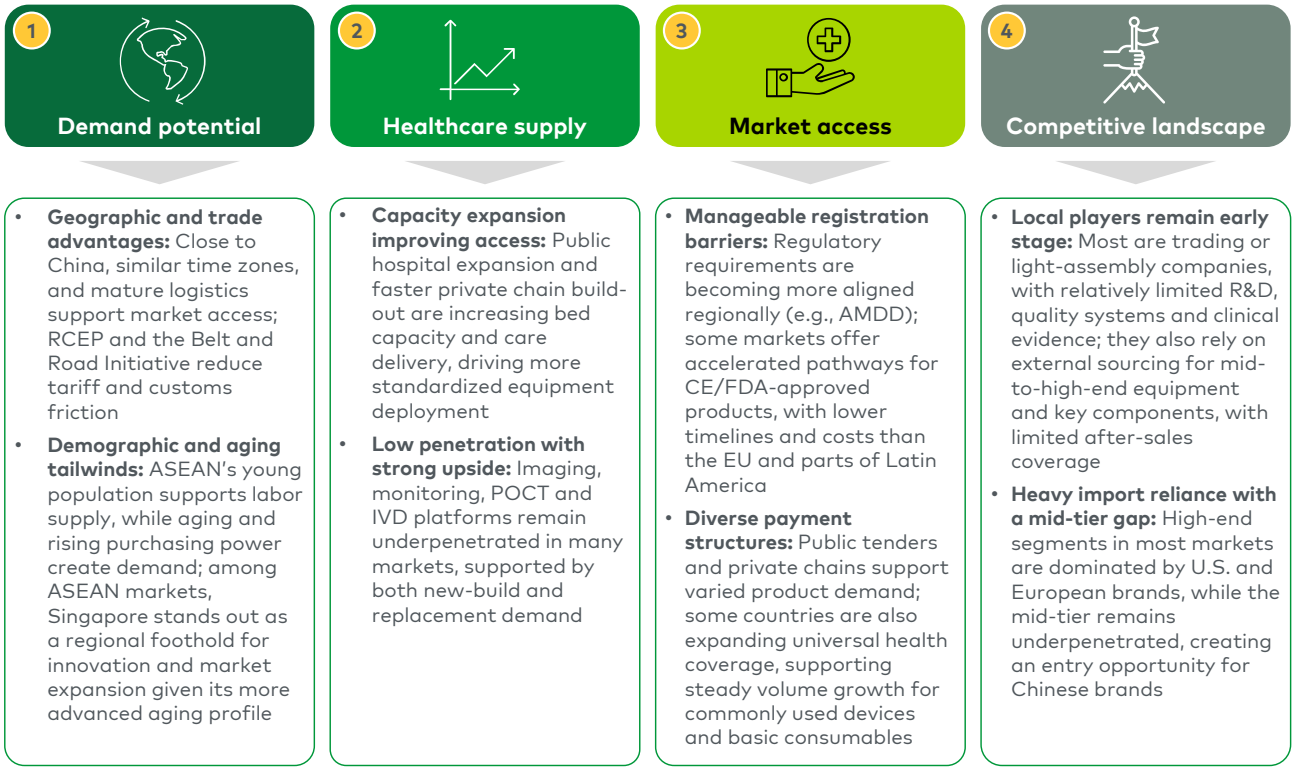
Note: JV=joint venture; KOL=key opinion leader
Source: L.E.K. analysis

2.1. Southeast Asia market selection and opportunity

2.1.1. Southeast Asia offers a favorable macro environment and strong market potential

Southeast Asia combines a favorable macro environment, strong market growth potential, moderate market access barriers and relatively underpenetrated competition, making it a preferred overseas expansion target for Chinese medtech companies. The section below assesses its attractiveness across four dimensions: demand potential, healthcare supply, market access and the competitive landscape.

Southeast Asia market attractiveness analysis

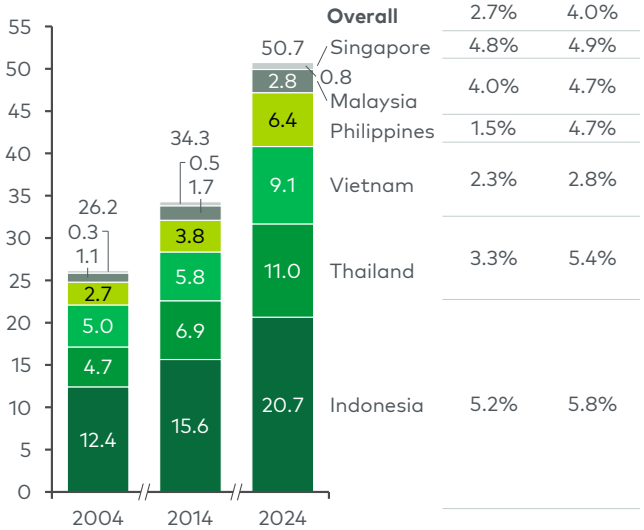


Note: RCEP=Regional Comprehensive Economic Partnership; AMDD=ASEAN Medical Device Directive; ASEAN=Association of Southeast Asian Nations; POCT=point-of-care testing; IVD=in vitro diagnostic; FDA=U.S. Food and Drug Administration
Source: L.E.K. analysis

2.1.2. Aging is reshaping population structure and creating underlying healthcare demand

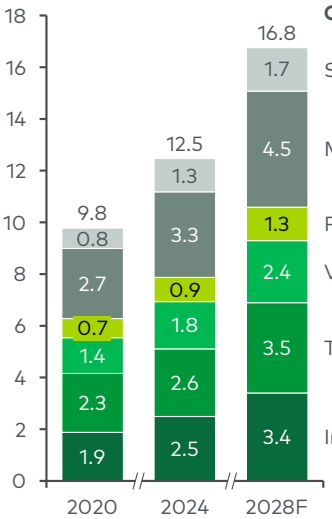
Continued expansion of the medical device market indicates strong long-term growth potential.

Population aged 65 and above in the SEA market* (2004, 2014, 2024)
People (millions)



	CAGR	
	2004-14	2014-24
Overall	2.7%	4.0%
Singapore	4.8%	4.9%
Malaysia	4.0%	4.7%
Philippines	1.5%	4.7%
Vietnam	2.3%	2.8%
Thailand	3.3%	5.4%
Indonesia	5.2%	5.8%

SEA medtech market size* (ex-factory price) (2020, 2024, 2028F)
USD (billions)



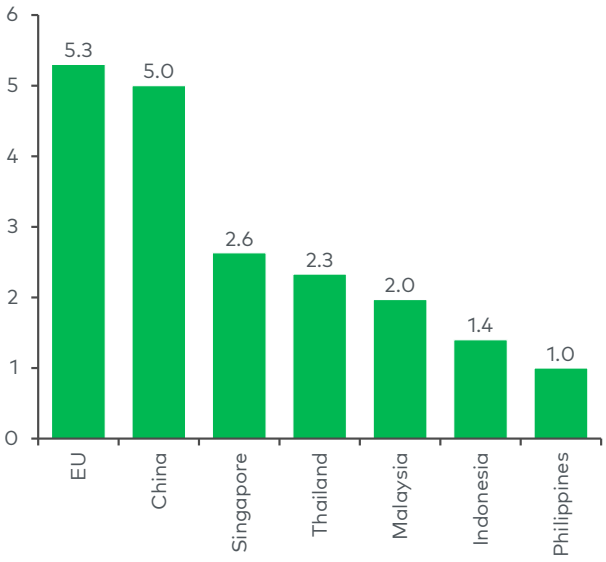
	CAGR	
	2020-24	2024-28F
Overall	6.3%	7.7%
Singapore	13.1%	6.8%
Malaysia	5.1%	8.0%
Philippines	6.1%	8.5%
Vietnam	7.2%	7.0%
Thailand	3.6%	7.5%
Indonesia	7.3%	8.1%

*Includes the six SEA countries
Note: SEA=Southeast Asia; CAGR=compound annual growth rate
Source: World Bank Group; Statista; L.E.K. analysis

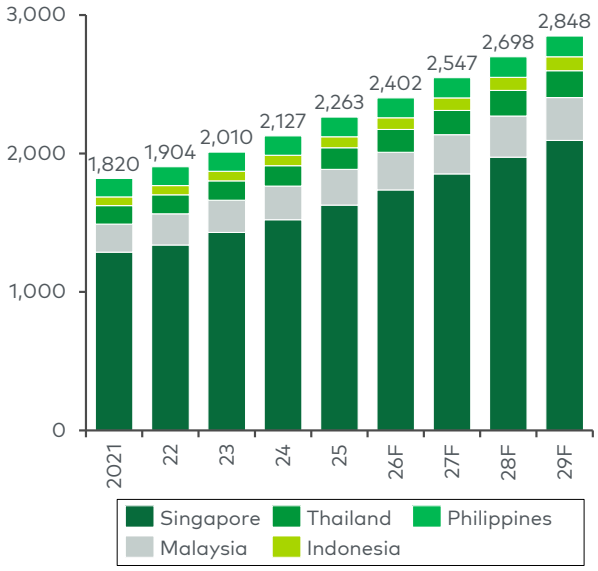
2.1.3. Southeast Asian countries are actively expanding healthcare infrastructure to meet growing demand

To meet rising demand for healthcare services, Southeast Asian countries are actively expanding basic healthcare infrastructure. As population structures shift, urbanization advances and the burden of chronic disease rises, demand for inpatient care is placing greater pressure on healthcare system capacity, while differences across countries in terms of resource allocation and healthcare spending intensity are becoming more visible. Overall, the region remains in a phase of closing infrastructure gaps while simultaneously expanding capacity, and healthcare investment levels are likely to continue rising alongside economic growth and greater public health spending, laying the foundation for long-term expansion of healthcare systems.

Hospital beds per capita by country (2020)
People (millions)



Inpatient healthcare spending per capita in Southeast Asic (2021-29F)
USD



Source: World Bank Group; Statista; L.E.K. analysis

Against the backdrop of accelerating innovation and technology iteration in the global medtech industry, regulatory systems across markets are also evolving to improve approval efficiency and accessibility while maintaining safety and effectiveness. Beyond traditional mature regulatory markets such as the U.S., Europe and Japan, Southeast Asian countries have also continued to increase investment in medtech regulatory system development in recent years, driving stronger regulatory capabilities and greater regional coordination.

As demand for medical technologies rises rapidly and healthcare systems across the region continue to upgrade, regulatory authorities in Southeast Asia are strengthening collaboration and actively advancing regulatory convergence and institutional development. For example, all 11 Association of Southeast Asian Nations (ASEAN) member states have implemented the ASEAN Medical Device Directive (AMDD), which

aims to harmonize regulatory requirements for medical devices and improve consistency and transparency across the region. At the country level, the Singapore Health Sciences Authority (HSA) is widely regarded as one of the more mature and internationally recognized regulatory agencies in the region, and has been formally recognized by Malaysia, Thailand, the Philippines and Australia as a reference regulatory authority for medical devices.

On this basis, while regulatory requirements across Southeast Asia continue to become more robust, the overall registration process also remains relatively efficient. Compared with mature markets such as the U.S. and Europe, average registration timelines are generally more compressed (see table below), creating favorable conditions for companies to accelerate market entry while maintaining compliance.

Comparison of medical device registration requirements and timelines

Country	Regulatory authority	ISO requirements	Clinical evaluation requirements	Registration timeline/duration
United States	U.S. Food and Drug Administration (FDA)	ISO 13485 Current Good Manufacturing Practice (CGMP)	More than 800 Class A/B devices are exempt from 510(k) submission Others require technical documentation and risk assessment	510(k): at least 90 days prior to launch
Germany	Federal Institute for Drugs and Medical Devices (BfArM)	ISO 13485	Class B devices require review under Annex III Implantable Class C devices require clinical evidence	Class B and C: over 1 year
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	Japanese Industrial Standards (JIS)	Class B/C devices with JIS standards: pre-market certification (Ninsho) Class B/C devices without JIS/ISO standards: pre-market approval (Shonin)	Class B: ~6 months Class C: 9–24 months
Singapore	Health Sciences Authority (HSA)	ISO 13485	Class B-D products already reviewed by a GHTF founding member may follow a simplified approval pathway	Class A: **60 business days** Class B-D: depends on risk class
Malaysia	Medical Device Authority (MDA)	ISO 13485 ISO 16412-1 ISO 16412-2 ISO 14155	Class C devices require clinical evaluation; overseas data may be accepted, but local data is preferred	**3-6 months**
Philippines	Food and Drug Administration (FDA Philippines)	ISO 13485 FDA/PMDA audit report	Risk assessment and clinical evidence are required	Class A: **1-2 months** Class B-D: 6-9 months
Vietnam	Department of Medical Equipment and Health Works (DMEHW)	ISO 13485	Clinical data is mandatory for Class C-D devices Devices with new functions or novel therapies must provide clinical trial data Overseas evaluation is accepted, but local bridging studies may be required	Class A: **7-10 days** Class B-D: 6-12 months
Indonesia	Directorate General of Pharmaceuticals and Medical Devices, Ministry of Health (Ditjen Farmalkes, Kemenkes)	ISO 13485 or GMP certification MDSAP or other regulatory certification may be accepted for imported products	Class B-D devices require a clinical evaluation report (overseas data may be accepted) Products with innovative technology or higher risk may require local clinical studies	Class A: **~1-3 months** Class B–C: ~6-9 months Class D: ~9-12 months
Thailand	Food and Drug Administration (FDA Thailand)	ISO 13485	Full technical documentation is required (previously limited to high-risk devices)	Class A: ~200 days Class B/C: ~250 days Class D: ~300 days

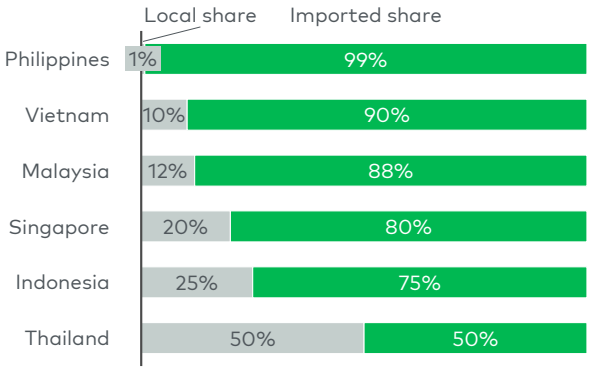
Source: Public information; L.E.K. analysis

Compared with other developed markets, Southeast Asia has **shorter average registration timelines and lower barriers to market entry**

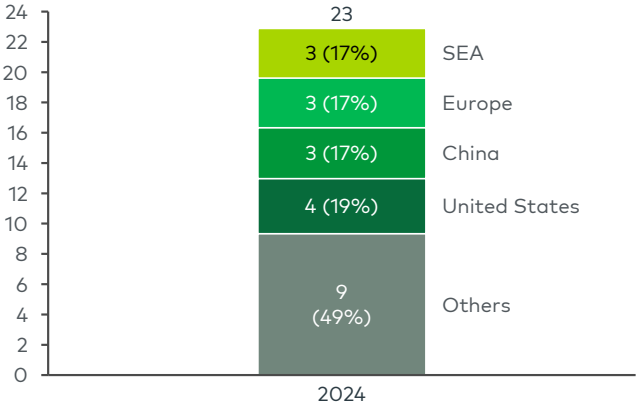
2.1.4. Local supply remains insufficient and import dependence is high, while Chinese medtech offers a strong value-for-money advantage

Across Southeast Asia, local supply of medical devices remains insufficient and markets continue to rely heavily on imports. At present, Europe and the U.S. remain the primary import sources, while Chinese medtech offers a compelling combination of value for money and product availability, creating room for further import share gains.

Share of imported medical devices by SEA market*
Percentage



Source countries of imported medical devices in SEA (2024)
USD (billions)



Heavy import reliance and limited local industry capacity: In major Southeast Asian markets, medtech self-sufficiency remains below 30%, indicating an early-stage value chain with limited R&D, technology and supply chain maturity, making scaled production and import substitution difficult

Supply remains concentrated in Europe and the U.S., while China is emerging as a key source market: Europe and the United States account for ~36% of imports, while China has become a key medical device supplier in SEA, supported by shorter lead times, mature technology and cost advantages

*Specific publication years were not disclosed; the information was published between 2022 and 2025
Note: SEA=Southeast Asia
Source: International Trade Administration website; Pure Global; L.E.K. analysis

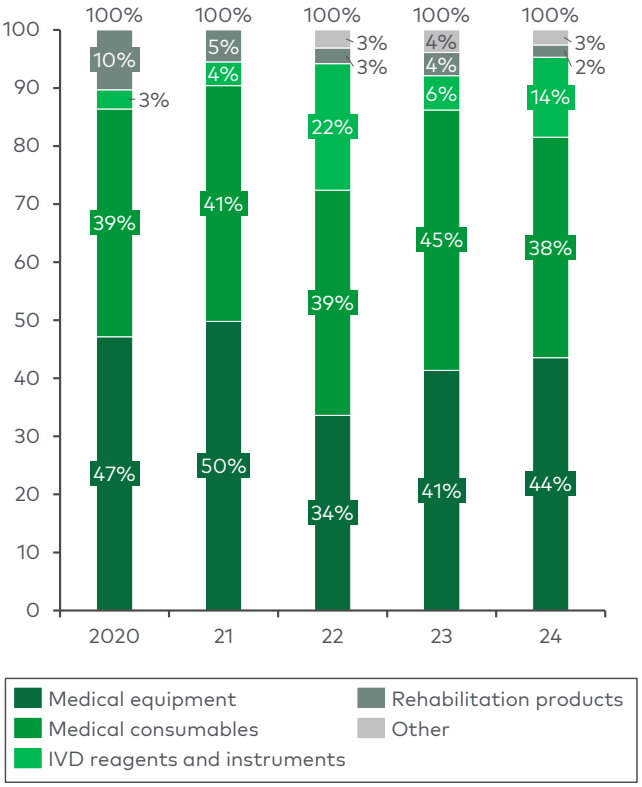
2.2. Southeast Asia product strategy and capability readiness

Building on earlier international expansion experience, Chinese companies have already achieved initial traction in selected product categories overseas. Only through precise market selection, differentiated product positioning and effective partner strategies can Chinese companies deliver steady growth and build competitive advantage in Southeast Asia. **To date, China's medtech companies have already made initial progress in going global, with relatively faster expansion seen in low-value consumables, mid-to-low-end devices and IVD.**

Category analysis for overseas expansion

China medical device exports by product category (by value) (2024)

Percentage



Overseas expansion rationale and representative companies

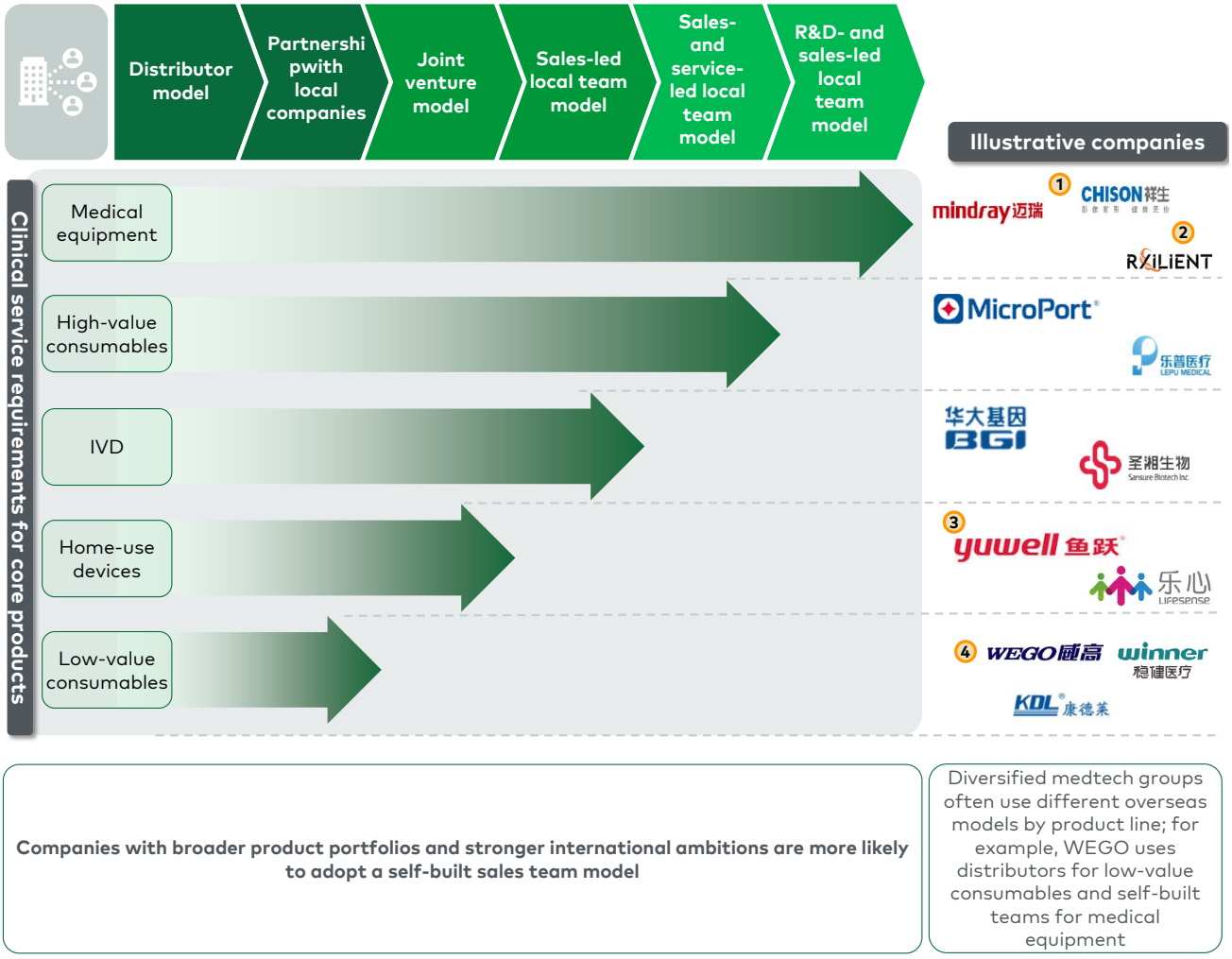
Low-value consumables	• Address **essential clinical dem** with strong overseas need • Mainly enter through OEM/ODM models • Chinese manufacturing offers a **cc advantage**
IVD	• Overseas operations **have reache scale** in selected segments - e.g., COVID testing and POCT • Rapid overseas growth in molecula diagnostics and chemiluminescence • Brand recognition and channel resources are strengthening
Medical equipment	• Internationalization of **mid-to-low-end devices** is already well established - e.g., ventilators and ultrasound • High-end segments are seeing grad breakthroughs - e.g., imaging and surgical rob
Low-value consumables	• More focused on clinical value, **with higher access barriers** • Supported by advantages in emerging technologies and cost • Require **channel build-out** and **localized team** capabilities

Note: IVD=in vitro diagnostic; POCT=point-of-care testing
Source: Frost & Sullivan; L.E.K. analysis

2.3. Southeast Asia go-to-market strategy and case studies

2.3.1. Companies with more complex core products and higher service requirements tend to adopt localized footprints

As clinical service requirements increase and operating models become more complex, companies are placing greater emphasis on localization in the course of international expansion. This is particularly true for product lines with high technical barriers that require ongoing physician education and intra-procedural support, where a distributor-only model is no longer sufficient to sustain competitiveness. As a result, these companies often choose to establish local teams directly in priority markets, enabling more precise responses to clinical needs while also helping build long-term brand trust and academic influence locally.



Note: IVD=in vitro diagnostic
Source: L.E.K. analysis

2.3.2. Case studies

2.3.2.1. Chison

A self-built team model driven by R&D and sales: Chison's Southeast Asia footprint covers six core markets: Singapore, Malaysia, Indonesia, Thailand, Vietnam and the Philippines. Overall, with the exception of Singapore, the company primarily adopts a distributor-led model across the region, relying on established local channels for registration, marketing and after-sales service. In some markets, only lightweight technical or service support resources are in place, and a full local team structure has not yet been established. This setup allows the company to control upfront investment while achieving relatively rapid multicountry market coverage.

At the regional strategy level, the company emphasizes "localization and rapid response," with a focus on product areas with clear demand and defined use cases, such as ultrasound imaging and point-of-care testing. During interviews, Chison noted: "The Southeast Asia market is highly segmented, and clinical needs and purchasing power vary significantly by

country. We need to adjust product configurations and service response accordingly, rather than simply replicating the China model." Accordingly, the company uses a regional support model to improve registration efficiency and product-market fit while strengthening technical support capabilities alongside its channel-driven approach.

Within this broader footprint, Singapore has been assigned a clearly differentiated strategic role. The company has positioned Singapore as its international headquarters outside China, covering key functions including R&D, manufacturing, quality and marketing while using a hub-and-spoke model to coordinate surrounding markets. As Chison noted: "Singapore is not just a sales market for us; it is also the platform through which we integrate Southeast Asia resources. Many regional decisions, quality system alignment efforts and communications with high-end customers are handled here." This positioning makes Singapore the center for regional coordination and capability export rather than simply another market node.

From an operating performance perspective, Singapore has already become an important growth engine for Chison's overseas business. As of June 2024, local revenue had reached approximately SGD 27 million, and the company plans to increase this to SGD 40 million-50 million by 2026. "Our goal in Singapore is not only to grow scale but, more importantly, to build a management and support system that can be replicated across neighboring markets." Looking ahead, Singapore is likely to further strengthen its role as a regional hub for operations, technical support and quality management, supporting Chison's scaled expansion across Southeast Asia.

Chison

Core products

Handheld ultrasound SonoEye series

Cart-based ultrasound XBit series

Portable ultrasound Sono Book series

Tablet Ultrasound Site~Rite*80

Headquarters information

Establishment: founded in 1996, with headquarters in Wuxi, Jiangsu Province

- **2024 revenue:** ~ RMB 470 million
- **Global footprint:** overseas revenue accounted for ~ **86%**
- **R&D investment:** ~17%

Southeast Asia footprint

- SEA primarily covers six core markets: **Singapore, Malaysia, Indonesia, Thailand, Vietnam and the Philippines;** distributor-led go-to-market model dominates; outside Singapore, most markets rely on established channel partners for registration, promotion, and after-sales support, with some markets supported only by lightweight technical or service functions rather than a full local team
- SEA strategy emphasizes localization and rapid response, focusing on high-demand segments such as ultrasound and POCT while leveraging a regional support model to improve market penetration, certification efficiency, and product-market fit
- **Singapore positioning: overseas international headquarters (Ex-China IHQ),** covering key functions including R&D, manufacturing, quality, and marketing; through a "hub-and-spoke" model, Singapore supports surrounding markets to enable integrated operations and scaled growth; as of June 2024, Singapore revenue had reached SGD 27M, with a 2026 target of SGD 40–50M

Chison's southeast Asia expansion journey

Initial exploration (2019-21)

- Global expansion strategy launched; Southeast Asia assessed, with Singapore selected as the first investment destination given its policy and innovation advantages
- Corporate headquarters and EDB supported local setup, helping the company navigate local regulations and market dynamics

Deepening localization and partnership (2022-24)

- CHISON SG PTE. LTD. was established in 2022; sales officially launched in 2023 alongside the acquisition of a product assembly plant
- An R&D agreement with NTU was signed in early 2024; sales grew by approximately 277% in the same year

Regional operating model taking shape (2025 onward)

- R&D investment to increase, with discussions underway with A*STAR on medical semiconductor chip collaboration and with NUS and ST Engineering on smart wearable device lab development
- Production capacity build-out to accelerate, including a second assembly site in Singapore; products assembled and exported from Singapore will be marketed under a new international brand

In SEA, Chison adopts a **self-built team model led by sales and service**: Local teams support sales and service for premium color ultrasound, portable and specialty devices, while the Singapore subsidiary advances an **integrated localized model across R&D, production and commercialization**; over the next 3-5 years, the company aims to further strengthen its regional network, build a Southeast Asia healthcare ecosystem and establish market leadership in premium ultrasound and specialty devices

Note: SEA=Southeast Asia; POCT=point-of-care testing; IHQ=international headquarters; EDB=Economic Development Board; NTU=Nanyang Technological University, NUS=National University of Singapore
Source: L.E.K. analysis

2.3.2.2. Rxilient

An in-licensing–driven expansion model across registration, development, manufacturing and commercialization, anchored by self-built local teams: As a key overseas platform within the CMS Group, Rxilient views emerging markets in developing countries as the core regions for its international expansion. Compared with mature markets in the U.S. and Europe, emerging markets such as Southeast Asia and the Middle East remain at an earlier stage of development in terms of pharmaceutical registration systems and commercialization capabilities. Market structures are more fragmented, and execution varies significantly across countries. While this increases market-entry complexity, it also creates room for companies with stronger integration capabilities to grow. As a result, Rxilient has not adopted a pure licensing or distributor model. Instead, it has chosen to build its own sales and service system while simultaneously advancing regional manufacturing support, gradually strengthening its local operating foundation.

During interviews, Rxilient noted: "Since China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017, the quality of new drug R&D and manufacturing has improved steadily. Many innovative drugs and highly differentiated generics now meet international standards. However, in recent years, centralized procurement in China has intensified competition, making domestic rivalry increasingly severe. For Chinese pharmaceutical companies going global, the choices are generally either the U.S. and Europe or emerging markets such as Southeast Asia, the Middle East and Latin America. Emerging markets are a better fit for our stage of development. Within Southeast Asia, the broader ASEAN environment is relatively stable, while Singapore offers transparent institutions and clear policies, making it a relatively certain landing point and a strong first stop for overseas expansion."

At the regional level, the company has adopted an umbrella structure, with Singapore serving as headquarters and radiating across Southeast Asia, the Middle East and other regions. From Singapore, Rxilient coordinates subsidiaries in Vietnam, Indonesia, Thailand, the Philippines, Malaysia and the United Arab Emirates while also supporting business development and operations in other emerging markets such as Australia and New Zealand, the Middle East, North Africa, and Latin America. At the same time, the company treats the build-out of local country teams as critical infrastructure to support the ongoing registration, market access and commercialization of innovative products entering local markets. The headquarters back-office team has already been established, and frontline teams covering sales, marketing, registration and market access have also been deployed in Singapore and local country markets. Regional headcount now exceeds 100, the majority of whom are in sales and marketing. As Rxilient noted: "Singapore does not only serve a regional management function; we have also built a full frontline team locally. If innovative products are handed entirely to distributors, it is difficult to execute academic promotion and training effectively. An in-house team provides much stronger assurance."

On the supply side, the company has partnered to establish a local manufacturing site in Singapore and has also invested in a plant in Indonesia to ensure supply stability and security.

Since establishing its Singapore regional headquarters at the end of 2021, the company has completed the build-out of its market infrastructure across countries, successfully registered multiple products and begun commercialization in each market. It is now moving into the next stage of scaled growth.

Rxilient

Core products

RXOLVE soothe eye drops

RXOLVE ultra eye drops

EmboLog® S

EyeOP1® glaucoma HIFU therapy

Headquarters information

Establishment: parent company established in Singapore in October 2021

Business positioning/ headquarters: global-local platform spanning product in-licensing, local development and registration, manufacturing and commercialization

Southeast Asia team

100+

employees

- Headquarters (Singapore) includes sales and back-office management
- Other markets are mainly staffed with frontline sales, market access and regulatory personnel

Southeast Asia footprint

- The company has established its regional headquarters in Singapore, overseeing central management functions including business development, central marketing, medical, regulatory, and back-office functions while also investing in local manufacturing; country markets including Singapore, Malaysia, the Philippines, Vietnam, Thailand and Indonesia are equipped with regulatory, sales and marketing teams
- Medical device business: currently centered on ophthalmic pharmaceuticals, with ophthalmic medical device activities advanced through sales and clinical promotion efforts

Rxilient's Southeast Asia expansion journey

Initial exploration (2021-22)
- Established in Singapore as part of CMS's globalization strategy, with an initial focus on building development, regulatory, sales and commercialization capabilities

Product in-licensing and localization (2022-24)
- From 2022 to 2023, offices were set up in Malaysia, Indonesia, the Philippines, Thailand, and Vietnam, with local teams established; in Singapore, a plant was set up in partnership with PharmaGend to support CDMO manufacturing
- Partnered with multiple companies, including Junshi Biosciences, to in-license innovative pharmaceutical products for development and commercialization in SEA

Full commercialization (2025 onward)
- Local market footprint completed, with products successfully launched across markets and frontline sales teams covering key hospitals and physician channels
- Built an integrated platform spanning product in-licensing, development and registration, CDMO manufacturing, and commercial sales

As an important overseas subsidiary of CMS, Rxilient adopts a **self-built team model driven by development and registration, sales, and manufacturing**. By building **frontline sales teams** across SEA, the company is steadily advancing innovative products in local markets through its own teams.

Note: CMS=China Medical System Holdings Ltd.; CDMO=contract development and manufacturing organization; SEA=Southeast Asia

2.3.2.3. Yuwell

A partnership model driven by sales: Southeast Asia is one of the most important growth regions in Yuwell's overseas footprint, contributing approximately one-quarter of overseas revenue and ranking among its faster-growing markets. Against the backdrop of rising demand for home health management and still-developing primary care systems across the region, the company continues to pursue a value-for-money strategy, with a focus on home-use medical products such as blood pressure monitors and oxygen concentrators. This positioning aligns well with the region's broad-based demand for basic medical devices and relatively high price sensitivity.

In terms of market entry, Yuwell has not chosen to build out large-scale in-house sales or manufacturing operations. Instead, it has adopted a distributor-led approach to achieve rapid market coverage through channel networks. During interviews, Yuwell noted: "Southeast Asia is highly fragmented, with significant differences across markets.

If we were to commit to a heavy-asset model from the outset, it would not necessarily be the most efficient approach. A more practical strategy is to first build out channels and place products directly into home-use settings." The company currently operates offices in Singapore, Vietnam and the Philippines while continuing to expand local distributor resources and strengthen end-customer reach through ecommerce platforms. Manufacturing and R&D remain concentrated in China, and the regional strategy places greater emphasis on channel penetration and brand building rather than shifting manufacturing capacity overseas.

At the regional level, Singapore plays more of a coordination and connectivity role. "What we value more is Singapore's role as a connector within the regional channel system, rather than the size of the market itself. It is an important platform for engaging distributors, participating in regional trade shows and integrating resources." Leveraging Singapore's mature business environment and exhibition resources, Yuwell uses the market to strengthen engagement with regional partners and support expansion across multiple countries.

From a development path perspective, Yuwell established a Thailand subsidiary in 2021 as its entry point into Southeast Asia, followed by a subsidiary in Indonesia in 2024 to strengthen localized operating capabilities. Looking ahead, the company will continue to expand its regional footprint through distributor networks and ecommerce channels. "We will gradually increase headcount and resource investment based on market feedback, but overall our pace will continue to be guided by sales efficiency and channel quality."

Overall, Yuwell adopts a partnership-driven model in Southeast Asia characterized by channel-first and asset-light operations: Market expansion is achieved through stronger distributor networks and the gradual build-out of local subsidiaries, while manufacturing and R&D remain concentrated in China. This strategy supports cost control and operating flexibility while also implying a relatively high reliance on channel coordination capabilities.

Yuwell

Core products

Yuwell 7F-5 oxygen concentrator

Yuwell blood pressure monitor

YX306 pulse oximeter

GU200 blood glucose and uric acid meter

Headquarters information

Establishment: founded in 1998, with headquarters in Danyang, Jiangsu Province

- **2024 revenue:** ~ RMB 7.6 billion
- **Global footpoint:** overseas revenue accounted for ~ **13%**
- **R&D investment:** ~ 7%

Southeast Asia team

~40

employees

- Thailand: **~20** employees
- Indonesia: **~10** employees
- Singapore: **1-2** expatriate sales staff
- The regional director is based across SEA, with extensive travel and roughly equal time spent in China and overseas

Southeast Asia footprint

- Yuwell first set up a subsidiary in Thailand and established a new one in Indonesia in 2024; it also operates offices in Singapore, Vietnam, the Philippines and other SEA markets while expanding local distributor channels
- Yuwell focuses on home-use products with a value-for-money positioning, well aligned with SEA demand, and has performed well in Thailand, Indonesia, Vietnam, the Philippines and Singapore
- Manufacturing and R&D remain concentrated in China, with no current plans for overseas manufacturing or R&D
- SEA is one of Yuwell's fastest-growing overseas markets, and the company may further increase investment in the region while steadily adding subsidiaries to expand market share

Yuwell's southeast Asia expansion journey

Initial exploration (2021)

- Established a Thailand subsidiary to begin localized expansion in SEA and create a springboard for broader regional expansion
- Started market development and early strategic partnerships

Deepening localization and partnership (2024)

- Established an Indonesia subsidiary to strengthen localized operations and market penetration
- Participated in leading medical trade shows across nine countries including Singapore and Thailand to enhance brand visibility and identify partners and channel resources

Regional operating model taking shape (2025 onward)

- Ongoing: expanding channels through distributors and e-commerce platforms to support product sales and market coverage across SEA
- Ongoing: replicating the "Thailand model" by applying successful localization experience to markets such as Indonesia and Vietnam

Driven by its value-for-money product strategy and overseas expansion ambitions, Yuwell's SEA approach centers on **developing partnerships and expanding distributor channels**, while strengthening localized operations through its Thailand and Indonesia subsidiaries; the company may also pursue M&A in the region to further build out its regional network

Note: SEA=Southeast Asia
Source: L.E.K. analysis

2.3.2.4. WEGO

An integrated development model: Southeast Asia is an important part of WEGO's overseas footprint and one of the key regional markets being prioritized in its international expansion. Rather than relying on a single expansion model, the company adopts a layered approach in Southeast Asia: General consumables are primarily distributed through channel partners, leveraging established distributor networks for scaled coverage, while the medical device business relies more on self-built teams to drive registration, hospital access and after-sales service, strengthening control over end-market execution. This product-tiered approach allows the company to strike a balance between cost control and service depth.

At the regional level, Singapore serves as the location of WEGO's Southeast Asia holding company and also functions as the regional headquarters for Southeast Asia, overseeing wholly owned subsidiaries in Vietnam, Indonesia, Thailand and other markets while managing coverage across all 11 ASEAN countries. Its primary responsibilities

include registration, trade coordination, subsidiary management, and broader regional coordination and back-office functions.

Man Zhang, Southeast Asia regional general manager of WEGO Overseas Group, noted: "Singapore is our strategic headquarters for Southeast Asia. We established our presence here not simply as a sales window but to build a regional platform that coordinates registration, trade, channels and subsidiary management. From brand image and compliance systems to cross-border coordination, Singapore provides us with a stable and international platform. In 2022, we established our overseas business division and registered a subsidiary in Singapore, beginning the systematic management of the Southeast Asia market. In 2023, we integrated our export and overseas management platforms and gradually strengthened our regional management capabilities. Over the past two years, our focus has been on registration and channel development to build core foundational capabilities. Over the next three to five years, we may consider establishing a regional training center depending on business maturity, although team expansion will continue to focus on sales, registration and regional management."

At the institutional level, Ms. Zhang further noted: "A Singapore registration certificate carries strong credibility and in some countries can support broader regional use, creating convenience for market access. On the R&D side, we continue to explore potential collaboration with local incubators and medical institutions, but at this stage our priority remains regional management and market expansion, with R&D investment to be assessed steadily in line with business development."

Overall, WEGO has developed an integrated model in Southeast Asia built on a layered product strategy and regional headquarters coordination: Low-value consumables remain channel-driven, while medical devices emphasize stronger local execution capabilities, with Singapore serving as the hub for regional coordination and resource integration. While this structure increases management complexity to some extent, it also creates room for collaboration across product lines.

WEGO

Core products

Novel minimally invasive posterior spinal tube

Co-axial introducer needles

X-ray blood irradiator

Disposable arterial cannula

Headquarters information

Establishment: founded in 1988, with headquarters in Weihai, Shandong Province

- **Global footprint:** overseas revenue accounted for ~**25%**

Southeast Asia team

>20

employees

- Regional general manager based in Singapore
- Singapore team: **2** employees responsible for SEA regional coordination
- Back-office support provided by headquarters

Southeast Asia footprint

- **Singapore: parent company + SEA regional headquarters**
  As the location of WEGO's **wholly owned parent company**, Singapore also serves as the **regional headquarters for SEA**, covering subsidiaries and offices in **Vietnam, Indonesia, Thailand**, and other markets; the team is primarily responsible for trade, registration, and channel development, while overseeing regional coverage across the 11 ASEAN markets
- The team is actively leveraging Singapore's local incubator resources and collaborating with institutions such as the **National Heart Centre and A*STAR** to advance joint R&D and innovation initiatives

WEGO's southeast Asia expansion journey

Initial exploration (2022-23)

- **2022:** the group established an overseas business division to accelerate international expansion and registered a subsidiary in Singapore to manage SEA markets
- **2023:** WEGO Overseas was established to integrate export and overseas management platforms

Localization and partnership deepening (2024-26)

- Completed registration for key products and accelerated market access while providing regulatory and trade support to SEA subsidiaries
- Built distributor networks and hospital platforms to drive hospital access and sales; training centers to be rolled out progressively based on business needs

Regional operating model taking shape (2027 onward)

- Advance innovation projects alongside clinical implementation and expand hospital partnerships
- Over the next 3-5 years, depending on market share progress, the company may establish a regional training center in Singapore to provide professional training and promotion support for surrounding markets

WEGO adopts an integrated SEA model: General consumables are mainly **distributed through channel partners**, while medical devices and high-value consumables are supported by **self-built teams** for sales and service, with localized operations advanced through its Thailand and Indonesia subsidiaries; over the next 3-5 years, the company may establish a regional training center in Singapore based on market share progress to strengthen its regional model

Note: SEA=Southeast Asia; ASEAN=Association of Southeast Asian Nations; A*STAR=Agency for Science, Technology and Research
Source: L.E.K. analysis

3. Anchoring in Singapore to expand across Southeast Asia

With a rich supply-side ecosystem, a well-developed industry chain, strong demand potential, clear political and geographic advantages, and supportive economic and cultural conditions, Singapore serves as both a strategic beachhead and an accelerator for medtech companies expanding into Southeast Asia.

Supply ecosystem

- **Industrial clustering and headquarters effects are well established:** dense concentration of multinational headquarters and manufacturing sites, with a well-developed supply chain that supports collaboration and outsourcing
- **Fast approvals with clear pathways:** multiple accelerated channels, short registration timelines and high predictability
- **A well-developed industry-academia-research translation network:** covering the full chain from R&D and validation to registration, manufacturing and application

Geographic advantages

- **Regional hub:** Singapore has a uniquely advantaged location in SEA, with any destination across the region reachable within a four-hour flight; within seven hours, it provides access to mainland China, India, South Korea, Japan, Australia and the Pacific Islands, making it an ideal springboard for Chinese companies expanding into international markets
- **Dense free trade network:** broad coverage under trade agreements such as RCEP and CPTPP enables flexible origin and supply chain planning
- **Connectivity and stability:** leading logistics and rule-of-law environment, low business risk and predictable cross-border operations

Robust demand

- **Strong demand for premium products and a benchmark market profile:** high per capita healthcare spending makes Singapore well suited for the launch and validation of high-value consumables and premium devices
- **High-quality healthcare and strong reference cases:** dense concentration of top-tier hospitals and specialty centers facilitates real-world evidence generation and KOL endorsement for broader replication

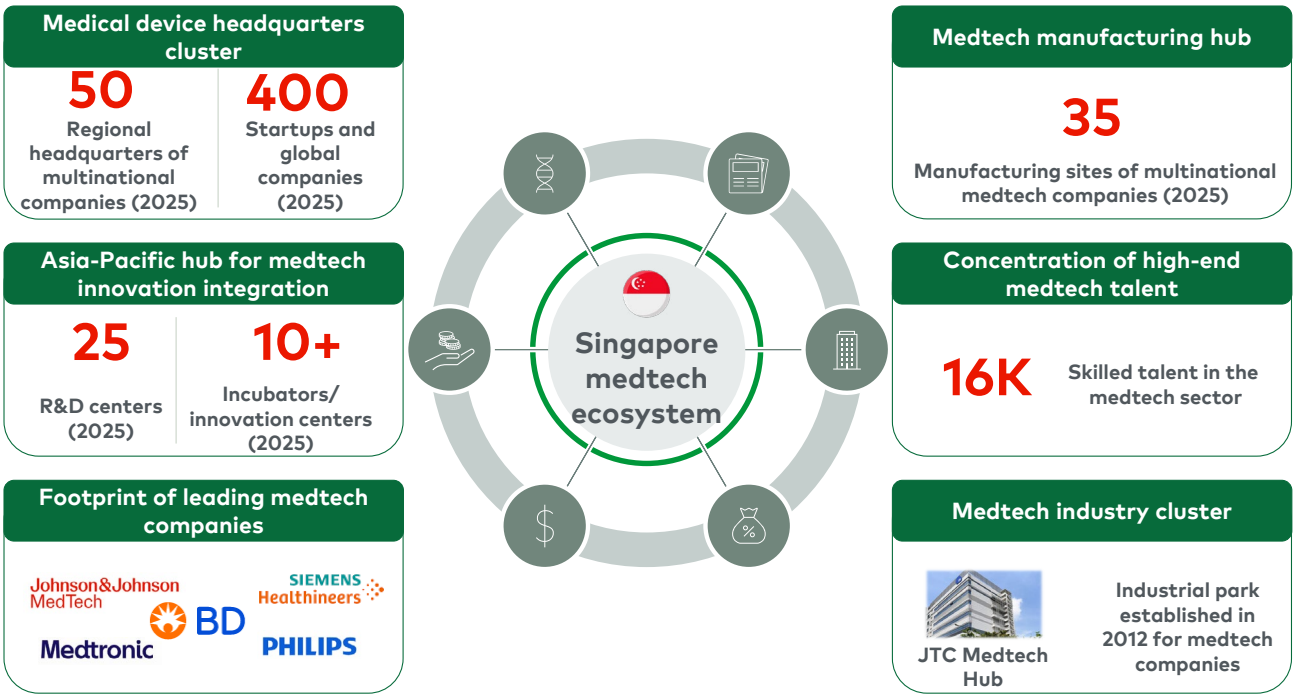
Economic and cultural conditions

- **Global financial and innovation hub:** deep concentration of capital and talent, with tighter access to treasury management and innovation partnerships
- **IP- and compliance-friendly:** strong intellectual property protection, an English-speaking business environment and lower compliance communication costs

Note: KOL=key opinion leader; SEA=Southeast Asia; RCEP=Regional Comprehensive Economic Partnership; CPTPP=Comprehensive and Progressive Agreement for Trans-Pacific Partnership; IP=intellectual property
Source: L.E.K. analysis

3.1. Headquarters economy as a growth driver: Building a complete medtech innovation and manufacturing ecosystem

As one of Asia's leading economic centers, Singapore is a major hub for regional headquarters of multinational companies. Benefiting from the concentration effects of its headquarters economy, the country has developed a complete ecosystem for medtech manufacturing, innovation and R&D, and talent supply.

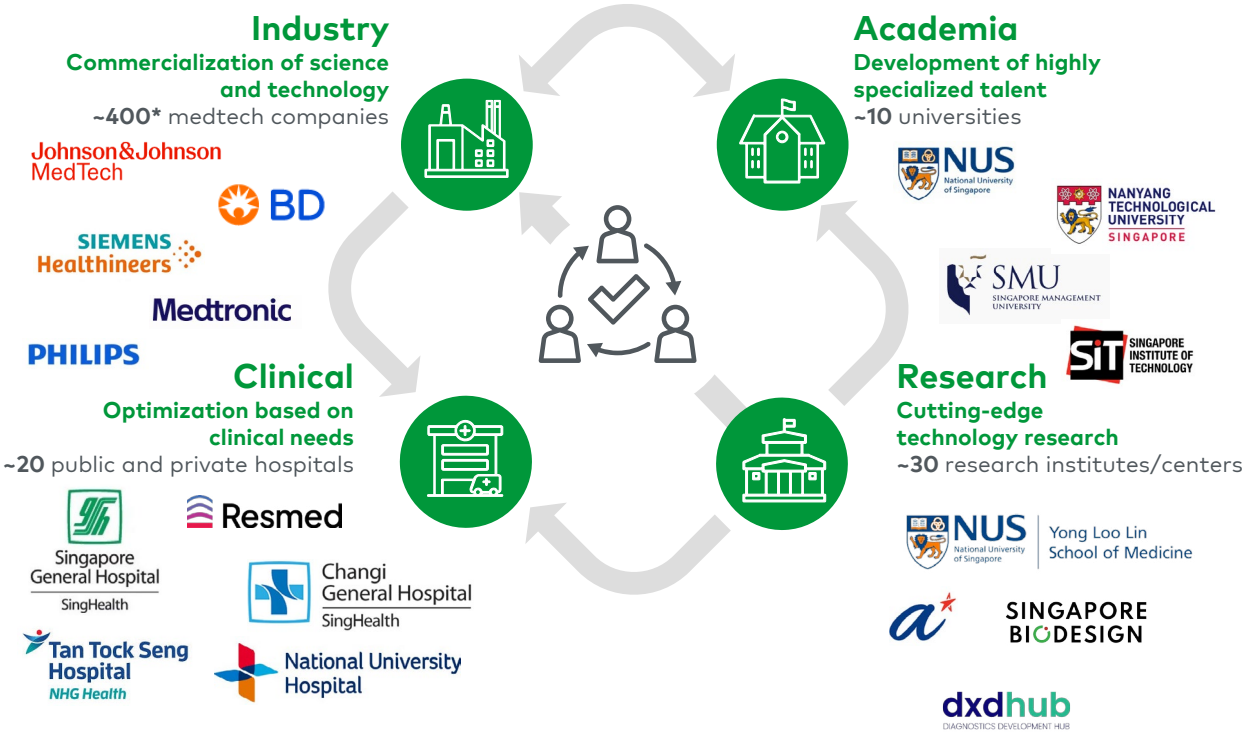


Source: Singapore Economic Development Board; L.E.K. analysis

3.2. Industry-academia-research-clinical collaboration: A well-developed innovation and translation support system

Singapore has a mature industry-academia-research-clinical ecosystem. Research institutes, universities, healthcare institutions and companies work closely together to provide comprehensive support for the development and execution of innovation projects, enabling medtech companies to accelerate technology validation, clinical trials and commercial application. Many companies have already used this model to bring innovation to market and expand their businesses.

Singapore "industry-academia-research-clinical" ecosystem



Singapore "industry-academia-research-clinical" case studies

Imaging and medical AI

In 2024, Siemens partnered with the National University Hospital of Singapore to **develop Spine AI, an AI-powered imaging interpretation system** for rapid lumbar lesion review; the product has entered clinical evaluation/pilot testing entered clinical evaluation/pilot testing

SIEMENS Healthineers × National University Hospital

High-value consumables

In 2022, Medairum partnered with Tan Tock Seng Hospital to develop personalized implant consumables; 200+ 3D models have been printed for clinical and teaching use, supporting **scaled adoption of 3D-printed consumables**

MEDAIRUM SHAPING HEALTHCARE × Tan Tock Seng Hospital NHG Health

Ophthalmology digitalization

In 2022, Johnson & Johnson Vision partnered with A*STAR to advance projects including MyoA*Bank and E-referral^, aiming to improve **care-seeking and screening rates** for eye diseases while optimizing healthcare resource allocation

Johnson&Johnson MedTech × Agency for Science, Technology and Research SINGAPORE

IVD

In 2024, Thermo Fisher, Mirxes and the National University Hospital of Singapore partnered to develop an **NGS-based cancer early screening solution**, which has entered the clinical validation stage

ThermoFisher SCIENTIFIC mirxes TO KNOW. TO ACT. × National University Hospital

Medtech manufacturing services

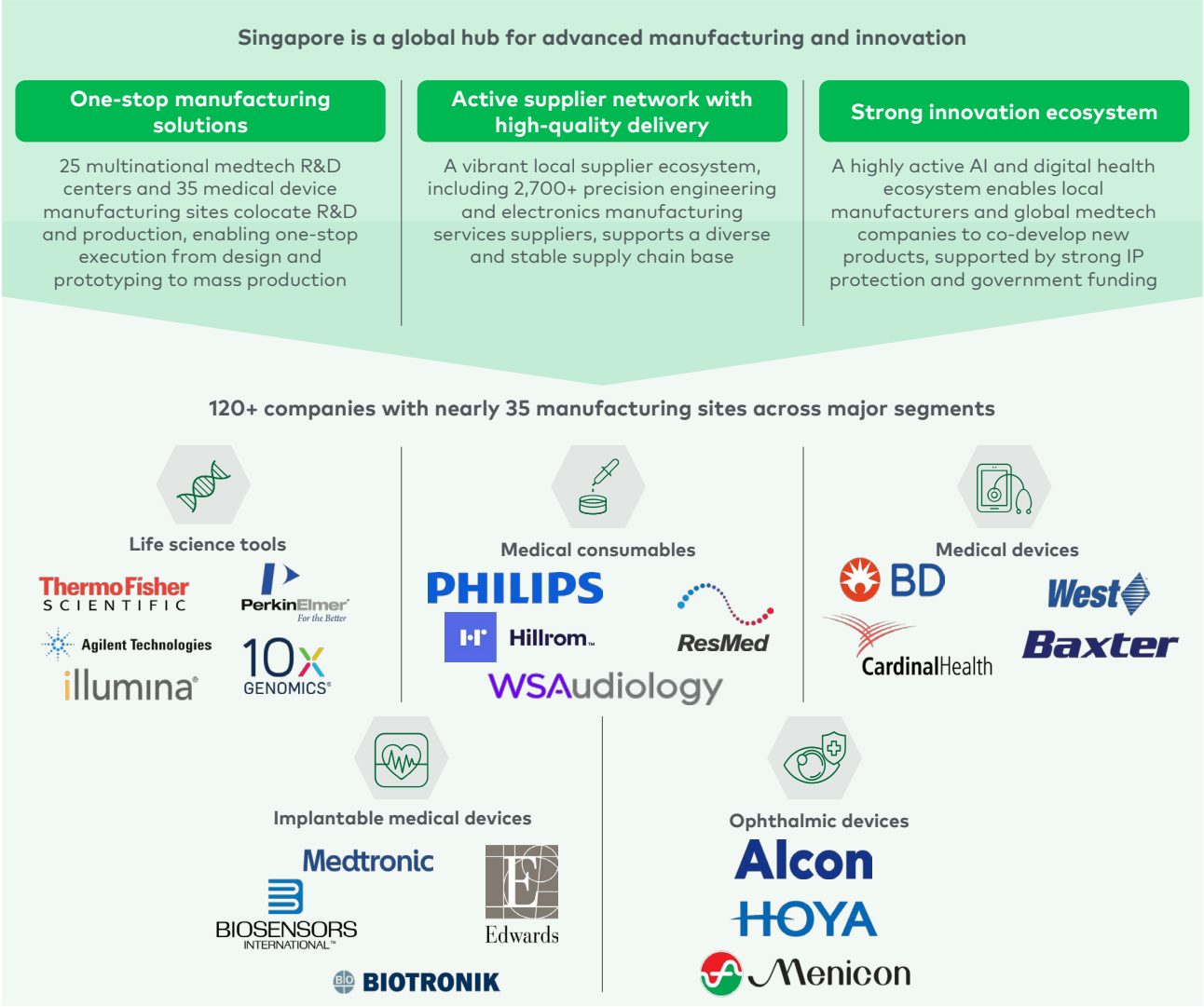
In 2025, ResMed leveraged its Singapore manufacturing base to strengthen production and assembly of key respiratory devices and improve regional supply chain coordination; the site now provides stable manufacturing and export support across multiple markets and has become an important part of the JS-SEZ regional supply chain

Resmed

*Including sales, manufacturing and service companies; ^MyoA*Bank is a data management platform that integrates anonymized data for ophthalmology research, while E-referral is an intelligent triage and referral system used to improve patient routing from primary care to specialty hospitals
Note: NGS=next-generation sequencing; AI=artificial intelligence; A*STAR=Agency for Science, Technology and Research; JS-SEZ=Johor-Singapore Economic Zone
Source: Company websites; L.E.K. analysis

3.3. Advanced manufacturing ecosystem: Connecting local capabilities with global markets

Singapore is widely recognized as one of Asia's leading hubs for advanced medtech manufacturing. Supported by a well-developed industry chain, mature R&D and manufacturing infrastructure, a highly skilled talent base, and a favorable policy environment, Singapore has attracted many multinational medtech companies to establish manufacturing sites and R&D centers locally. It offers not only high-quality manufacturing capabilities but also rigorous quality management and internationally recognized certification systems that can support the global supply of high-end medical devices and innovative products. In addition, Singapore's close connectivity with Southeast Asia and global markets makes it an important hub for companies expanding regionally and building a broader global footprint.



Note: AI=artificial intelligence; IP=intellectual property
Source: Singapore Economic Development Board; L.E.K. analysis

3.4. Connecting Southeast Asia, Asia-Pacific and global markets

Singapore not only sits at the geographic crossroads of Southeast Asia and the broader Asia-Pacific but also is widely regarded as a two-way gateway linking regional and global markets, supported by its advanced transportation and logistics infrastructure, stable business environment and extensive free trade network with major global economies. This hub position helps companies expand across regional markets and integrate supply chains while enabling faster access to global resources and technological capabilities.

Accordingly, Singapore's role as a two-way gateway is reflected in both its logistics and trade connectivity across Southeast Asia and the broader Asia-Pacific and its function as a platform for global companies to expand operations, integrate resources and access technology, providing practical support for both regional expansion and global coordination.

Singapore as a "two-way gateway" to global markets

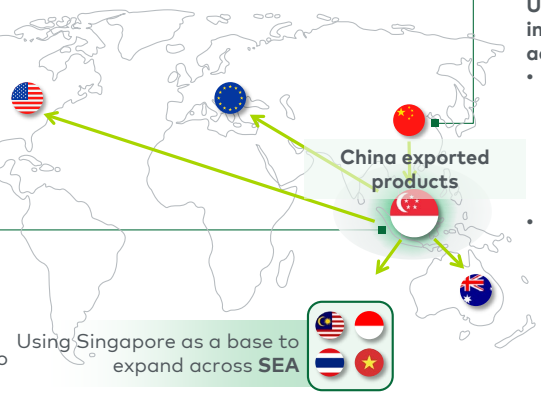
meiban® we shape your ideas **Meiban case study**

Using Singapore as a launchpad for global expansion

- Founded in Singapore, Meiban leverages the country's mature medtech supply chain and testing and validation capabilities to enable efficient coordination from design and pilot production to regulatory support, shortening product development and launch timelines
- The company has gradually evolved into an end-to-end CDMO serving global medtech and health tech customers, validating products and manufacturing capabilities in Singapore before replicating them overseas to support regional-to-global expansion

Strategic footprint in the JS-SEZ

- Singapore serves as the hub for engineering, quality, and project management, while the JS-SEZ connects to manufacturing sites in Johor, Malaysia, providing access to lower-cost production resources
- Through Singapore-Johor cross-border coordination, Meiban combines high-value engineering with scaled, cost-efficient manufacturing, improving supply chain resilience and cost efficiency while supporting customers' scaled production across SEA and global markets



WEGO威高 **WEGO case study**

Using Singapore as an international expansion hub to accelerate overseas growth

- **Since 2022**, WEGO has advanced its globalization strategy by positioning Singapore as its SEA regional hub, accelerating global coordination across R&D, manufacturing and services
- Leveraging Singapore's stable business environment and well-established supply chain, WEGO connects efficiently with global customers through its wholly owned subsidiary, supporting exports and strengthening brand visibility

Providing funding and operational support for access to U.S., European and international markets

- WEGO leverages Singapore's financial and business environment to secure international funding, such as IFC financing, while strengthening SEA-based manufacturing, R&D and supply chain capabilities to support expansion into U.S. and European markets
- Drawing on Singapore's international certification systems and management experience, such as MDSAP, WEGO ensures quality and regulatory alignment with global standards, shortens time to market and builds cross-border operating capabilities

With its strategic location and mature industry ecosystem, Singapore serves as a "two-way gateway" linking **SEA, the broader Asia-Pacific and global markets**

Note: CDMO=contract development and manufacturing organization; JS-SEZ=Johor-Singapore Special Economic Zone; SEA=Southeast Asia;
IFC=International Finance Corporation; MDSAP=Medical Device Single Audit Program
Source: Company websites; L.E.K. analysis

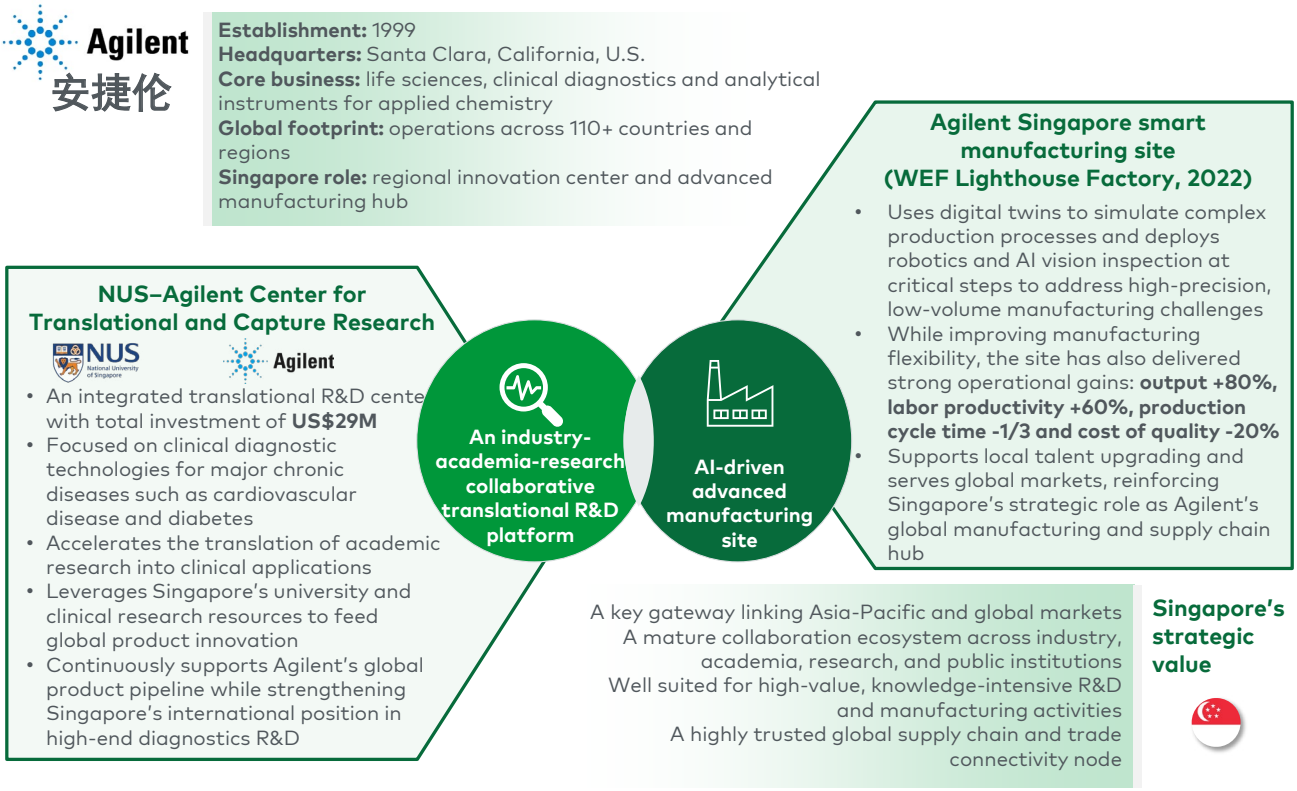
Against this backdrop, Singapore's strategic significance as a global gateway now extends well beyond traditional trade and geographic advantages. It increasingly lies in the country's ability to systematically integrate global innovation resources and high-end industrial capabilities. Supported by a stable and transparent institutional environment, deep international connectivity and a mature collaboration framework spanning industry, academia, research and public institutions, Singapore provides multinational companies with a platform that efficiently connects frontier R&D, advanced manufacturing and global market demand. For companies, this not only reduces the complexity of cross-border coordination and operations but also significantly improves the efficiency with which innovation is translated and scaled.

This advantage is especially pronounced in knowledge- and technology-intensive sectors such as life sciences and advanced instrumentation. Singapore can support companies in building deep partnerships with local universities and research institutes to translate basic research into clinical and commercial applications while also hosting highly complex advanced manufacturing activities with demanding quality and reliability requirements and serving international markets through its global supply chain network. Agilent's footprint in Singapore has gradually taken shape and deepened within this system. Its experience across both translational R&D and smart manufacturing clearly illustrates how Singapore can provide multinational companies with an integrated platform spanning R&D, manufacturing and global markets while also strengthening local innovation capabilities and technical talent over time.

In practice, Agilent partnered with the National University of Singapore to establish the Center for Translational and Capture Research, with total investment of **US$29 million**, focused on developing more precise clinical diagnostic approaches for cardiovascular disease and diabetes. At the same time, Johnson & Johnson Innovation's JLABS Singapore has accelerated the translation of early-stage research into innovative therapies through close collaboration with local incubators and strategic partners. Collaboration models such as these allow companies to fully leverage Singapore's local research capabilities and also contribute to the development of the broader innovation ecosystem.

In advanced manufacturing, Agilent's Singapore site was recognized as a **World Economic Forum Lighthouse Factory in 2022**. To address the production challenges associated with low-volume, high-mix, high-precision products, the site introduced digital twin technology to simulate and optimize production processes, while deploying robotics and artificial intelligence-based vision inspection systems at critical steps. The result was a significant improvement in both productivity and quality: Output increased by approximately 80%, labor productivity rose by approximately 60%, production cycle time was reduced by nearly one-third and cost of quality declined by approximately 20%. At the same time, this transformation upgraded the capabilities of the local technical workforce, shifting more of their work toward data-driven troubleshooting and process optimization rather than repetitive manual tasks while further supporting supply to global markets.

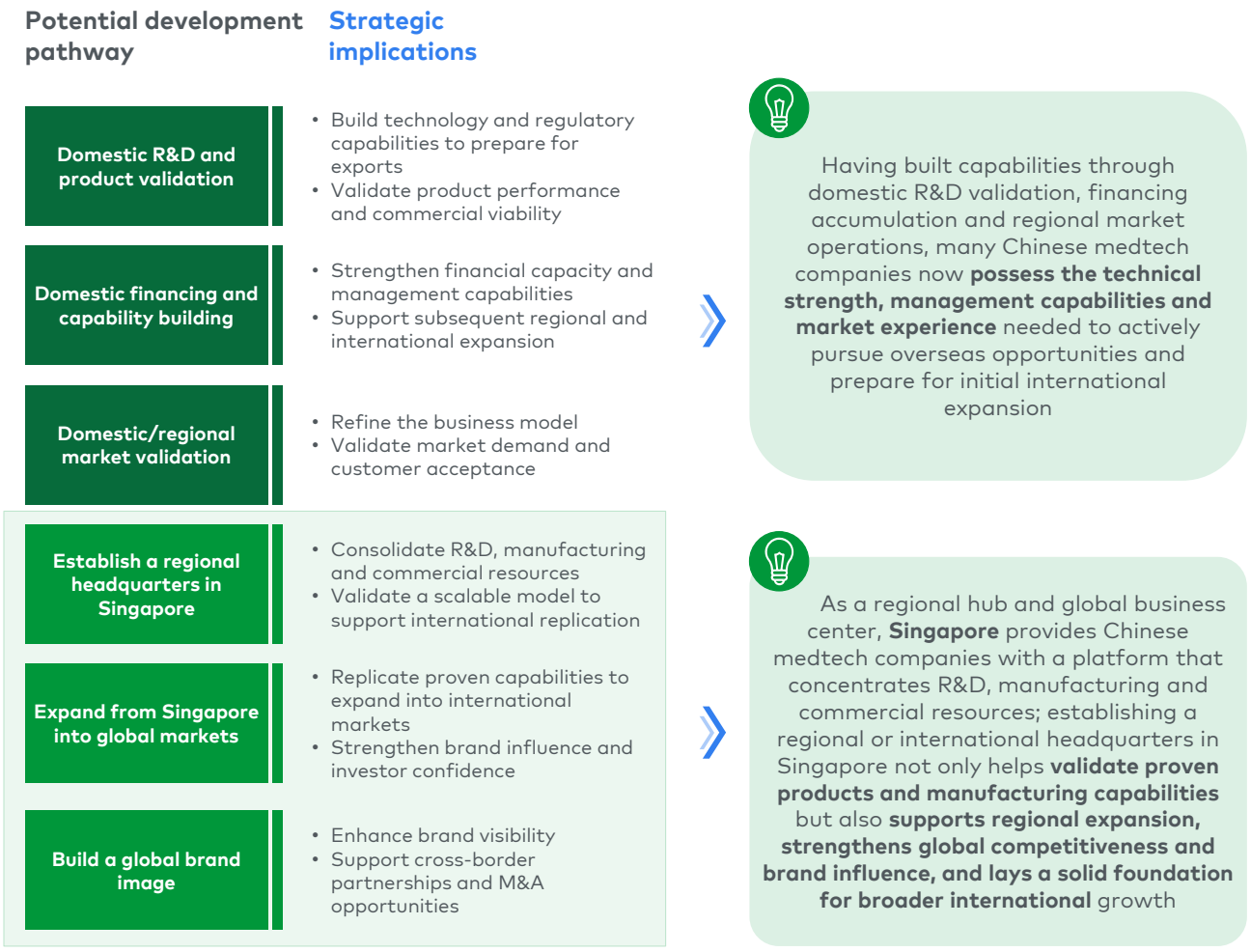
Taken together, these examples highlight Singapore's hub role in multinational companies' global value chains and demonstrate its systemic advantages in integrating innovation, manufacturing and global markets. They also provide a compelling reference point for other companies considering investment and expansion in Singapore.



Note: AI=artificial intelligence; WEF=World Economic Forum
Source: Singapore Economic Development Board; L.E.K. analysis

3.5. Strategic evolution: From domestic growth to Singapore headquarters and global expansion

Against the backdrop of increasing connectivity across regional and global markets, a growing number of companies are evolving from domestic market operations toward an international footprint anchored in Singapore. This has gradually emerged as a representative development pathway. Along this path, companies can pursue multiple possibilities across organizational structure, operating model and market coverage, creating room for different future directions and strategic choices.



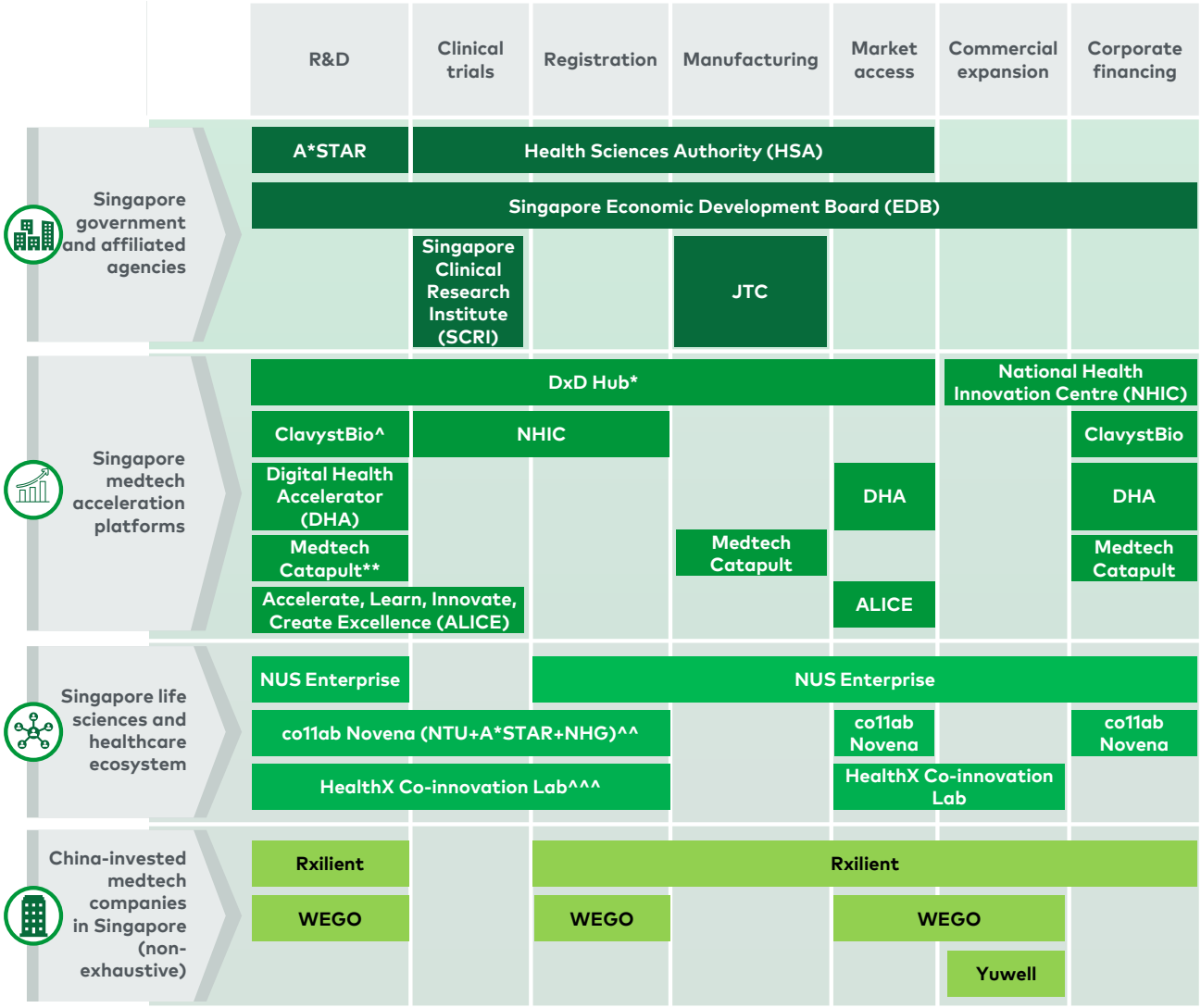
Source: L.E.K. analysis

3.6. End-to-end support for global expansion: Singapore enables medtech companies' international growth

Singapore provides medtech companies with systematic support across the full value chain of global expansion — with well-developed enabling systems and policy support spanning product R&D, regulatory approval, commercialization, financing and talent access — helping companies advance regional expansion and business execution efficiently.

Singapore, together with its government agencies and broader life sciences ecosystem, provides medtech companies with systematic support across the full value chain of global expansion, spanning R&D, clinical trials, regulatory approval, manufacturing, market access, commercial expansion and corporate financing. With a mature industry-academia-research-clinical innovation ecosystem and an efficient industrial services network, companies can leverage local incubators, research institutions and international

collaboration platforms to integrate resources quickly, refine business models, and advance regional expansion and business execution more effectively, accelerating the full journey from R&D to commercialization. This strong combination of policy support, resource availability and innovation infrastructure materially improves the efficiency of regional expansion and business execution, providing a solid foundation for going global.



*DxD Hub is a national platform under A*STAR covering the full chain from R&D and registration to manufacturing and market access; it is differentiated here as its scope differs materially from A*STAR's core activities **Singapore MedTech Catapult's core mandate is to accelerate the development and industrialization of novel medical devices and technologies; the platform provides startups and small and medium-sized enterprises with one-stop services spanning product design, functional prototyping, regulatory validation and commercial manufacturing, with a focus on life sciences and medtech ^ClavystBio is a biopharma-focused investment platform under CLA Real Estate Holdings, a Temasek subsidiary ^^co11ab was jointly established by Nanyang Technological University, A*STAR and the National Healthcare Group ^^^HealthX Co-innovation Lab is Singapore's first local healthtech innovation lab, jointly launched by Synapxe and Amazon Web Services

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About the Authors

Stephen Sunderland
Stephen Sunderland is Head of L.E.K. Consulting's Asia-Pacific region, with over 20 years of consulting experience. Based in Singapore, Stephen is a member of L.E.K.'s Executive Committee and a board member and leads L.E.K.'s Healthcare and Life Sciences practice in Southeast Asia. He advises medtech clients spanning high-value implantables, capital equipment, consumables, diagnostics and research tools on profitable growth strategies, including market entry and growth acceleration, major tendering, manufacturing strategy and due diligence.

Grace Wang
Grace Wang is a Partner based in L.E.K. Consulting's Shanghai office. She joined the firm in 2012, and has supported international and Chinese clients in medical device, pharmaceutical, life science tools and broader healthcare sectors on a wide range of engagements including growth strategy, pricing and market access, China localization and transaction support. Grace holds a bachelor's in management science from Fudan University in China, and a double master's in international management from Fudan University and Bocconi University in Milan.

Wonder Wang
Wonder Wang is Senior Engagement Manager at L.E.K. Consulting with over 10 years of experience in the life sciences sector, specializing in MedTech strategy and investment research across the Asia-Pacific region. With a background in Biomaterials Engineering, he has led multiple strategic initiatives focused on industry trends, regulatory landscapes, and market entry strategies. Prior to L.E.K., he worked for a private equity firm, where he supported the development and investment of MedTech platforms in China. His expertise includes innovation commercialization, regional market expansion, and healthcare ecosystem development, with a focus on advancing Asia-Pacific MedTech innovation globally.

About the Singapore Economic Development Board

The Singapore Economic Development Board (EDB), a government agency under the Ministry of Trade and Industry, is responsible for strategies that enhance Singapore's position as a global centre for business, innovation, and talent. We undertake investment promotion and industry development, and work with international businesses, both foreign and local, by providing information, connection to partners and access to government incentives for their investments. Our mission is to create sustainable economic growth, with vibrant business and good job opportunities for Singapore and Singaporeans. For more information on EDB, please visit **www.edb.gov.sg**.

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